

US3032110 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:46:53

All time stamps listed in this document are displayed in GMT

US3032110

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

[Participant ID](#)

US3032110

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

US3032110

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Date of Birth (MMM yyyy)	(b) (6)	1958
Age		61
Age Units		YEARS
Age (Derived)		61
Sex	Female	<input checked="" type="radio"/>
	Male	<input type="radio"/>
Ethnicity	Hispanic or Latino	<input type="radio"/>
	Not Hispanic or Latino	<input checked="" type="radio"/>
	Not Reported	<input type="radio"/>
	Unknown	<input type="radio"/>
Race (Check All That Apply)		
White		True
Black		False
Asian		False
American Indian or Alaska Native		False
Native Hawaiian or other Pacific Islander		False
Other		False
If race is Other, specify _____		
Unknown		False
Not reported		False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 16:57:28

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 16:57:28

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 16:57:28

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Sep 2020 16:57:28

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:20:58

Generated On: 09 Jun 2021 14:46:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	5 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	18:40 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 18:40
Height (<i>xxx.x</i>)	158.8 cm
Weight (<i>xxx.x</i>)	72.6 kg
BMI (<i>xxx.x</i>)	28.78960 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) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Sep 2020 16:57:28

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Date of assessment (dd MMM yyyy) 5 AUG 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) UN UNK 1998

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 16:57:28

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 16:57:28

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 101477

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Oct 2020 13:46:20

Generated On: 09 Jun 2021 14:46:53

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Oct 2020 13:46:20

Generated On: 09 Jun 2021 14:46:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 AUG 2020
Time of assessment (00:00-23:59)	18:40 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 18:40
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Oct 2020 13:46:20

Generated On: 09 Jun 2021 14:46:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 AUG 2020
Time of assessment (00:00-23:59)	20:30 (24 HR)
Vital Signs Date and Time (derived)	5 AUG 2020 20:30
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

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) 5 AUG 2020

What was the treatment time? (00:00-23:59) 19:59 (24 HR)

Treatment Date and Time (derived) 5 AUG 2020 19:59

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 AUG 2020
Collection time (00:00-23:59)	19:14 (24 HR)
Collection date and time (derived)	5 AUG 2020 19:14

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Collection date (dd MMM yyyy)			5 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:57	5 AUG 2020 18:57
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 20:32

PC Open Date & Time

05 AUG 2020 20:19

PC Close Date & Time

05 AUG 2020 22:49

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	05 AUG 2020 23:44
PC Open Date & Time	05 AUG 2020 23:44
PC Close Date & Time	06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

06 AUG 2020 20:29

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 12:00

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 00:14

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 05:59

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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 AUG 2020 05:59

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 10:55

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 20:33

PC Open Date & Time

05 AUG 2020 20:19

PC Close Date & Time

05 AUG 2020 22:49

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

05 AUG 2020 23:45

PC Open Date & Time

05 AUG 2020 23:44

PC Close Date & Time

06 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 20:30

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 12:01

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 00:14

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 06:00

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 06:00

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 10:55

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 20:34
PC Open Date & Time	05 AUG 2020 20:19
PC Close Date & Time	05 AUG 2020 22:49

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 23:46
PC Open Date & Time	05 AUG 2020 23:44
PC Close Date & Time	06 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 20:31
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 12:02
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 00:15
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 06:00
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 06:00
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 10:56
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3032110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 01 Oct 2020 21:50:12

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

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)	8 SEP 2020
Time of assessment (00:00-23:59)	14:59 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 14:59
Temperature (xxx.x)	36.8 C
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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

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)	8 SEP 2020
Time of assessment (00:00-23:59)	16:40 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 16:40
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3032110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3032110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 16:03 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 16:03

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

US3032110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	15:32 (24 HR)
Collection date and time (derived)	8 SEP 2020 15:32

US3032110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:17	8 SEP 2020 15:17
Nasopharyngeal Swab 2	No		

US3032110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐
No ☒

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

PC Time Stamp 08 SEP 2020 16:38

PC Open Date & Time 08 SEP 2020 16:23

PC Close Date & Time 08 SEP 2020 18:53

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	08 SEP 2020 19:49
PC Open Date & Time	08 SEP 2020 19:48
PC Close Date & Time	09 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 23:26

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

11 SEP 2020 09:50

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

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

11 SEP 2020 23:38

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 23:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 SEP 2020 22:41

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 00:12

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 16:39

PC Open Date & Time

08 SEP 2020 16:23

PC Close Date & Time

08 SEP 2020 18:53

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

08 SEP 2020 19:49

PC Open Date & Time

08 SEP 2020 19:48

PC Close Date & Time

09 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 23:27

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 09:50

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 23:38

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 23:53

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 22:41

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 00:12

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 16:39
PC Open Date & Time	08 SEP 2020 16:23
PC Close Date & Time	08 SEP 2020 18:53

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 19:50
PC Open Date & Time	08 SEP 2020 19:48
PC Close Date & Time	09 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 23:32
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

98 of 2791

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 09:51
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2791

EAB) (1725)

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 23:39
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 23:54
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 22:42
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

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 ☒

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 01 Oct 2020 21:50:12

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 01 Oct 2020 21:50:12

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Oct 2020 19:30:45

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Oct 2020 19:30:45

Generated On: 09 Jun 2021 14:46:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 15:30
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Oct 2020 19:30:45

Generated On: 09 Jun 2021 14:46:53

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.

US3032110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Oct 2020 19:30:45

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

15:59 (24 HR)

Collection date and time (derived)

13 OCT 2020 15:59

US3032110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Oct 2020 19:30:45

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 17:18:37

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 OCT 2020 08:54:31

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 22:04:11

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	03 NOV 2020 13:09:53
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 12:06:03

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☐

Yes ☒

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

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

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

Date and time of submission

29 NOV 2020 18:36:35

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 12:49:18

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 00:01:51

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 09:13:07

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 08:51:55
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 12:07:35

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 02:01:27

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 09:06:52

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

22 JAN 2021 08:23:03

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

30 JAN 2021 07:00:36

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 00:02:14

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 00:01:27
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	21 FEB 2021 23:57:42
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 17:40:00

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 18:58:48

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 19:30:37

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 18:00:04

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 18:59:22

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 12:00:29

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 18:27:53

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Date and time of submission

23 APR 2021 16:38:02

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Date and time of submission

30 APR 2021 12:37:46

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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°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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 MAR 2022 00:01
Patient Cloud Close Date & Time	15 MAR 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 APR 2022 00:01
Patient Cloud Close Date & Time	05 APR 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUN 2022 00:01
Patient Cloud Close Date & Time	07 JUN 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Date and time of submission

Patient Cloud Open Date & Time	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
---	-------------------

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2022 00:01
Patient Cloud Close Date & Time	20 SEP 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3032110

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:46:53

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		02 MAR 2021 17:40:16

US3032110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 24 Nov 2020 20:28:23

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 24 Nov 2020 20:28:23

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Dec 2020 20:07:09

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Dec 2020 20:07:09

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Feb 2021 19:39:13

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Feb 2021 19:39:13

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Feb 2021 19:39:13

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Feb 2021 19:39:13

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:33:01

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	17 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:33:01

Generated On: 09 Jun 2021 14:46:53

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) _____

US3032110

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:33:01

Generated On: 09 Jun 2021 14:46:53

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.

US3032110

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:33:01

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	09:29 (24 HR)
Collection date and time (derived)	17 MAR 2021 09:29

US3032110

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:33:01

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:33:01

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:33:01

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 20 Nov 2020 16:29:20

Generated On: 09 Jun 2021 14:46:53

Date of Contact	19 NOV 2020
Time of Contact	11:20
Date and Time of Contact (derived)	19 NOV 2020 11:20
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

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Form: Symptom Log (1)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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 NOV 2020
------	-------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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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Form: Symptom Log (1)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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 19 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	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 19 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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 NOV 2020
------	-------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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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Form: Symptom Log (2)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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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Form: Symptom Log (2)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	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 19 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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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Form: Symptom Log (3)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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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Form: Symptom Log (3)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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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Form: Symptom Log (3)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	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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Form: Symptom Log (4)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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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Form: Symptom Log (4)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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 19 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	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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Form: Symptom Log (5)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	15 NOV 2020
------	-------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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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Form: Symptom Log (5)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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 19 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	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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Form: Symptom Log (6)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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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Form: Symptom Log (6)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	16 NOV 2020
------	-------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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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Form: Symptom Log (6)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	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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Form: Symptom Log (7)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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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Form: Symptom Log (7)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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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Form: Symptom Log (7)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	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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Form: Symptom Log (8)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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

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Form: Symptom Log (8)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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Form: Symptom Log (8)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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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Form: Symptom Log (9)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	98 %	
O2 Saturation Units	%	
Temperature	36.7 C	
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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (9)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 ☐

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Form: Symptom Log (10)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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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Form: Symptom Log (10)

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	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	92 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (10)

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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 ☐

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Form: Symptom Log (11)

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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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Form: Symptom Log (11)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

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Data signed: (b) (4) 25 Mar 2021 14:17:26

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

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Form: Symptom Log (11)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 ☐

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	95 %	
O2 Saturation Units	%	
Temperature	96.9 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 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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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"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	95 %	
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 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 25 Mar 2021 14:17:26

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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Form: Symptom Log (13)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 ☐

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Form: Symptom Log (14)

Data signed: (b) (4) 25 Mar 2021 14:17:26

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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"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	93 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (14)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	96 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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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Form: Symptom Log (15)

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Generated On: 09 Jun 2021 14:46:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 19 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 25 Mar 2021 14:17:26

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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 ☐

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 checked="" 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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Form: Symptom Log (16)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	93 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (16)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 ☐

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Form: Symptom Log (17)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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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Generated On: 09 Jun 2021 14:46:53

	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	97 %	
O2 Saturation Units	%	
Temperature	98.9 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 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Generated On: 09 Jun 2021 14:46:53

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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"/>

PRODUCTION RELEASE (v12.003

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 ☐

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 type="checkbox"/>
Day 18	<input checked="" 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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Form: Symptom Log (18)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	96 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (18)

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Generated On: 09 Jun 2021 14:46:53

	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 19 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (19)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" 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 19 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	94 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (19)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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"/>

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" 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"/>

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	95 %
---------------	------

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 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 19 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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"/>

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" 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 19 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	01 DEC 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.8 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 19 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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 19 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 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 checked="" 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 19 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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	02 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
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 19 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Nov 2020 20:28:22

Generated On: 09 Jun 2021 14:46:53

Date of Visit 19 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 19 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) 1

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 20 NOV 2020

End Date 26 NOV 2020

Oxygen Saturation 92 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 25 Mar 2021 14:17:26

Generated On: 09 Jun 2021 14:46:53

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 20 Nov 2020 16:29:21

Generated On: 09 Jun 2021 14:46:53

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 07 Jan 2021 19:15:51

Generated On: 09 Jun 2021 14:46:53

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	21 NOV 2020
Day 5	Yes	23 NOV 2020
Day 7	Yes	25 NOV 2020
Day 9	Yes	27 NOV 2020
Day 14	Yes	2 DEC 2020
Day 21	Yes	09 DEC 2020
Day 28	Yes	16 DEC 2020

US3032110

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 20 Nov 2020 16:29:21

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Nov 2020 16:29:21

Generated On: 09 Jun 2021 14:46:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 NOV 2020
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 11:28
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032110

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Nov 2020 16:29:21

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 NOV 2020

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

US3032110

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 20 Nov 2020 16:29:21

Generated On: 09 Jun 2021 14:46:53

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 NOV 2020

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Dec 2020 15:53:19

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Dec 2020 15:53:19

Generated On: 09 Jun 2021 14:46:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 DEC 2020
Time of assessment (00:00-23:59)	15:33 (24 HR)
Vital Signs Date and Time (derived)	16 DEC 2020 15:33
Height (xxx.x)	158.8 cm
Weight (xxx.x)	71.0 kg
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Dec 2020 15:53:19

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 DEC 2020

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

US3032110

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 07 Jan 2021 19:15:51

Generated On: 09 Jun 2021 14:46:53

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 DEC 2020

US3032110

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:23:18

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	18 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3032110

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:10:51

Generated On: 09 Jun 2021 14:46:53

Date of updated informed consent (<i>dd MMM yyyy</i>)	18 FEB 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>)	18 FEB 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

US3032110

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 17:23:18

Generated On: 09 Jun 2021 14:46:53

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3032110

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:23:18

Generated On: 09 Jun 2021 14:46:53

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	18 FEB 2021
Time of assessment (00:00-23:59)	11:58 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 11:58
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3032110

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:23:18

Generated On: 09 Jun 2021 14:46:53

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	18 FEB 2021
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 13:15
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3032110

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

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:23:18

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 FEB 2021

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

US3032110

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

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:23:18

Generated On: 09 Jun 2021 14:46:53

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) 18 FEB 2021

What was the treatment time? (00:00-23:59) 12:42 (24 HR)

Treatment Date and Time (derived) 18 FEB 2021 12:42

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

US3032110

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 17:23:18

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 FEB 2021

Collection time (00:00-23:59)

11:40 (24 HR)

Collection date and time (derived)

18 FEB 2021 11:40

US3032110

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 17:23:18

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 FEB 2021
Collection time (00:00 - 23:59)	11:45
Collection Date and Time (derived)	18 FEB 2021 11:45

US3032110

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

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:23:18

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:10:51

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:10:51

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:10:50

Generated On: 09 Jun 2021 14:46:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	17 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 21:10:50

Generated On: 09 Jun 2021 14:46:53

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)	17 MAR 2021
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 09:25
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 21:10:50

Generated On: 09 Jun 2021 14:46:53

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	17 MAR 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 11:20
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3032110

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:10:50

Generated On: 09 Jun 2021 14:46:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 MAR 2021

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

US3032110

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 21:10:50

Generated On: 09 Jun 2021 14:46:53

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) 17 MAR 2021

What was the treatment time? (00:00-23:59) 10:45 (24 HR)

Treatment Date and Time (derived) 17 MAR 2021 10:45

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

US3032110

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:10:50

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 15:33:01

Generated On: 09 Jun 2021 14:46:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032110

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:33:01

Generated On: 09 Jun 2021 14:46:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032110

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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 _____

US3032110

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

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)	

US3032110

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

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.

US3032110

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3032110

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Nov 2020 16:29:20

Generated On: 09 Jun 2021 14:46:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3032110

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 19:19:54

Generated On: 09 Jun 2021 14:46:53

AEID	USA-US032-2020-MRNA-1273-P30 1000013
Adverse event	COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	11 NOV 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)	1 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032110

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Apr 2021 19:19:54

Generated On: 09 Jun 2021 14:46:53

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

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

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

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
HYPOTHYROIDISM

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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

Name of Medication LIOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
HYPOTHYROIDISM

Dose per administration 5

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: MUSCLE
SPASMS OF LOWER BACK

Dose per administration 15

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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US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
HYPERCHOLESTEROLEMIA

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: ACID
REFLUX

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF SEASONAL
INFLUENZA

Dose per administration 0.5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

	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)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION

Dose per administration 6

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

	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)	18 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)	24 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"/>

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

	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 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)		19 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

	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)	20 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)	23 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"/>

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 18:06:04

Generated On: 09 Jun 2021 14:46:53

	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)		20 NOV 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3032110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Sep 2020 16:57:28

Generated On: 09 Jun 2021 14:46:53

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:46:53

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 ☐

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 07 Jan 2021 19:15:51

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US032-2020-MRNA-1273-P301000013
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 07 Jan 2021 19:15:51

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US032-2020-MRNA-1273-P301000013
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/NOV/2020 14:55
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

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 07 Jan 2021 19:15:51

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US032-2020-MRNA-1273-P301000013
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	01/DEC/2020 20:06
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

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 07 Jan 2021 19:15:51

Generated On: 09 Jun 2021 14:46:53

SAEID	USA-US032-2020-MRNA-1273-P301000013
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KEITH
Investigator's Last Name	VRBICKY
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/DEC/2020 18:58
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.	True

Audit

US3032110 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032110

Form: Participant Creation

Generated On: 09 Jun 2021 14:46:53

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 14:25:02
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'US3032110'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:49:11

US3032110

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:05:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:49:27

US3032110

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:05:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:49:12

US3032110

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:05:23
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:49:27

US3032110

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'SCRN'	System	06 Aug 2020 01:49:27

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered (b) (6) 1958'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:49:13

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '61'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'YEARS'	System	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '61'	System	06 Aug 2020 01:05:25

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit 2 Day 29: Sex (Female) recorded on this form does not match with the Sex (Male) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).		13 Nov 2020 09:29:59
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit 2 Day 29: Sex (Female) recorded on this form does not match with the Sex (Male) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' answered with 'data is correct as entered' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	16 Oct 2020 16:32:06
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit 2 Day 29: Sex (Female) recorded on this form does not match with the Sex (Male) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:37:35
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:57:29
User entered 'Female (F)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:46:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:21
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:06

US3032110

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:05:25

US3032110

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Aug 2020'	System	06 Aug 2020 01:05:25

US3032110

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '2020'	System	06 Aug 2020 01:05:25

US3032110

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Amendment 1 (1)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:05:25

US3032110

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:05:25

US3032110

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:05:25

US3032110

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:05:25

US3032110

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:05:25

US3032110

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:24
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 23:49:12

US3032110

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:46:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'I'	System	06 Aug 2020 01:05:30

US3032110

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:46:53

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:37:36
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:05:30

US3032110

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:46:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:38:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:51:56

US3032110

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 14:00:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 14:00:10
Data point term sent to Coder	System	06 Aug 2020 13:58:34
User entered 'hypothyroidism'	Kelsey Kelley (b) (4)	06 Aug 2020 13:58:17

US3032110

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 1980'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:17

US3032110

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:17

US3032110

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:17

US3032110

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:17

US3032110

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:17

US3032110

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Jan 1980'	System	06 Aug 2020 13:58:17

US3032110

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '1980'	System	06 Aug 2020 13:58:17

US3032110

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered empty.	System	06 Aug 2020 13:58:17

US3032110

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:46:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered empty.	System	06 Aug 2020 13:58:17

US3032110

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 14:01:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 14:01:10
Data point term sent to Coder	System	06 Aug 2020 13:59:36
User entered 'hypercholesterolemia'	Kelsey Kelley (b) (4)	06 Aug 2020 13:58:42

US3032110

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 2019'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:42

US3032110

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:42

US3032110

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:42

US3032110

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:42

US3032110

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:42

US3032110

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Jan 2019'	System	06 Aug 2020 13:58:42

US3032110

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '2019'	System	06 Aug 2020 13:58:42

US3032110

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered empty.	System	06 Aug 2020 13:58:42

US3032110

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:46:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered empty.	System	06 Aug 2020 13:58:42

US3032110

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 14:01:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 14:01:10
Data point term sent to Coder	System	06 Aug 2020 13:59:36
User entered 'acid reflux'	Kelsey Kelley (b) (4)	06 Aug 2020 13:58:54

US3032110

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 2018'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:54

US3032110

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:54

US3032110

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:54

US3032110

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:54

US3032110

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:58:54

US3032110

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Jan 2018'	System	06 Aug 2020 13:58:54

US3032110

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '2018'	System	06 Aug 2020 13:58:54

US3032110

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered empty.	System	06 Aug 2020 13:58:54

US3032110

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:46:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered empty.	System	06 Aug 2020 13:58:54

US3032110

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Aug 2020 07:25:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 07:25:30
Data point term sent to Coder	System	06 Aug 2020 14:01:40
User entered 'muscle spasms of lower back'	Kelsey Kelley (b) (4)	06 Aug 2020 14:00:41

US3032110

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 2019'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:00:41

US3032110

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:00:41

US3032110

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:00:41

US3032110

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:00:41

US3032110

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:00:41

US3032110

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Jan 2019'	System	06 Aug 2020 14:00:41

US3032110

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '2019'	System	06 Aug 2020 14:00:41

US3032110

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered empty.	System	06 Aug 2020 14:00:41

US3032110

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:46:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered empty.	System	06 Aug 2020 14:00:41

US3032110

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 14:03:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 14:03:14
Data point term sent to Coder	System	06 Aug 2020 14:01:40
User entered 'cholecystectomy'	Kelsey Kelley (b) (4)	06 Aug 2020 14:01:01

US3032110

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 2017'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:01:01

US3032110

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:01:01

US3032110

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:01:01

US3032110

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 2017'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:01:01

US3032110

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:01:01

US3032110

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Jan 2017'	System	06 Aug 2020 14:01:01

US3032110

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '2017'	System	06 Aug 2020 14:01:01

US3032110

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Jan 2017'	System	06 Aug 2020 14:01:01

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:46:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '2017'	System	06 Aug 2020 14:01:01

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 14:03:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 14:03:13
Data point term sent to Coder	System	06 Aug 2020 14:01:41
User entered 'cholecystitis'	Kelsey Kelley (b) (4)	06 Aug 2020 14:01:36
	(b) (4)	

US3032110

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 2017'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:01:36

US3032110

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:01:36

US3032110

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:01:36

US3032110

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 2017'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:01:36

US3032110

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:01:36

US3032110

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Jan 2017'	System	06 Aug 2020 14:01:36

US3032110

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '2017'	System	06 Aug 2020 14:01:36

US3032110

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Jan 2017'	System	06 Aug 2020 14:01:36

US3032110

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:46:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '2017'	System	06 Aug 2020 14:01:36

US3032110

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	(b) (4) 17 Sep 2020 15:50:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4) 17 Sep 2020 15:50:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4) 06 Aug 2020 14:03:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	(b) (4) 06 Aug 2020 14:03:19
Data point term sent to Coder	System	06 Aug 2020 14:02:45
User entered 'complete hysterectomy'	Kelsey Kelley (b) (4)	06 Aug 2020 14:02:19

US3032110

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	8 Apr 2021 18:52:04
DataPoint Verified.		6 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 1998'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:02:19

US3032110

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:02:19

US3032110

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:02:19

US3032110

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 1998'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:02:19

US3032110

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:02:19

US3032110

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Jan 1998'	System	06 Aug 2020 14:02:19

US3032110

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '1998'	System	06 Aug 2020 14:02:19

US3032110

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Jan 1998'	System	06 Aug 2020 14:02:19

US3032110

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:46:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '1998'	System	06 Aug 2020 14:02:19

US3032110

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Aug 2020 14:03:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 14:03:19
Data point term sent to Coder	System	06 Aug 2020 14:02:46
User entered 'menorrhagia'	Kelsey Kelley (b) (4)	06 Aug 2020 14:02:46

US3032110

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 1990'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:02:46

US3032110

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:02:46

US3032110

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:02:46

US3032110

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 1998'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:02:46

US3032110

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:01
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:02:46

US3032110

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Jan 1990'	System	06 Aug 2020 14:02:46

US3032110

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '1990'	System	06 Aug 2020 14:02:46

US3032110

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'Jan 1998'	System	06 Aug 2020 14:02:46

US3032110

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:46:53

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '1998'	System	06 Aug 2020 14:02:46

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:52:57

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:52:57

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '18:40'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:52:57

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '5 Aug 2020 18:40'	System	06 Aug 2020 01:52:57

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '158.8' cm	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:52:57
DataPoint set to visible.	(b) (4) System	06 Aug 2020 01:05:30

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '72.6' kg	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:52:57
DataPoint set to visible.	(b) (4) System	06 Aug 2020 01:05:30

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
Amendment Manager: User entered '28.78960'	System	16 Sep 2020 23:44:53
User entered '28.8'	System	06 Aug 2020 01:52:57
DataPoint set to visible.	System	06 Aug 2020 01:05:30

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'kg/m2'	System	06 Aug 2020 01:52:57
DataPoint set to visible.	System	06 Aug 2020 01:05:30

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 01:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:58
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page and the unit should not remain (ND for "Not done" and not left empty). Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 04:44:49
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page and the unit should not remain (ND for "Not done" and not left empty). Please update accordingly. ' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 15:30:42
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 15:30:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 15:30:38
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page and the unit should not remain (ND for "Not done" and not left empty). Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:12:36
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:57:29
User entered '36.5' C	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:52:57

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:58
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	06 Oct 2020 15:30:38
	(b) (4)	
User entered empty; reason for change New Information	Kelsey Kelley (b) (4)	06 Oct 2020 15:30:38
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
	(b) (4)	
User entered 'Oral (Oral)'	Kelsey Kelley (b) (4)	06 Aug 2020 01:52:57
	(b) (4)	

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:52:57

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 01:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:58
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 04:44:51
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' answered with 'updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 15:30:46
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 15:30:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	06 Oct 2020 15:30:38
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:12:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:57:29
User entered '69'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:52:57

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'bpm'	System	06 Aug 2020 01:52:57

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:58
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 15:30:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 15:30:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '16'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:52:57
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'breaths/min'	System	06 Aug 2020 01:52:57

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:58
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 15:30:38
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	06 Oct 2020 15:30:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '139'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:52:57
	(b) (4)	

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'mmHg'	System	06 Aug 2020 01:52:57

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (7)(A)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Oct 2020 15:20:58
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	06 Oct 2020 15:30:38
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Kelsey Kelley (b) (4)	06 Oct 2020 15:30:38
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
	(b) (4)	
User entered '89'	Kelsey Kelley (b) (4)	06 Aug 2020 01:52:57
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'mmHg'	System	06 Aug 2020 01:52:57

US3032110

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04

US3032110

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:53:03

US3032110

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 10:01:10
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 23:05:51
User entered '5 Aug 2020'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:53:03

US3032110

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:57:07

US3032110

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:57:07

US3032110

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:57:07

US3032110

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:57:07

US3032110

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'un UNK 1998'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:57:07

US3032110

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:57:07

US3032110

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:57:07

US3032110

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:46:53

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:40:58
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:57:07

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 01:50:35
	(b) (4)	

US3032110

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'l'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:46:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 01:41:42
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:35

US3032110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:41:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:49

US3032110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:41:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:49

US3032110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:41:55
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:50:49

US3032110

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'VISIT1'	System	06 Aug 2020 01:50:49

US3032110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 00:19:11

US3032110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
	System	21 Aug 2020 02:24:58
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:24:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 00:19:11
User entered '101477' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 00:19:11

US3032110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 00:19:11

US3032110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

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)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:12:23

US3032110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

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)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:12:23

US3032110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:12:23

US3032110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:12:23

US3032110

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:46:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:12:23

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:46:20
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:22:42
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'DATA CORRECTION MADE' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 13:49:38
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 13:49:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 13:49:33
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:00:37
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:57:29
User entered '158.8' cm	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:46:20
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	09 Oct 2020 13:49:33
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	09 Oct 2020 13:49:33
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
	(b) (4)	
User entered '72.6' kg	Kelsey Kelley (b) (4)	06 Aug 2020 14:04:38
	(b) (4)	

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:46:20
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:22:42
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'DATA CORRECTION MADE' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 13:49:38
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 13:49:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 13:49:33
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:00:37
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:57:29
User entered '158.8' cm	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:46:20
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	09 Oct 2020 13:49:33
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	09 Oct 2020 13:49:33
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
	(b) (4)	
User entered '72.6' kg	Kelsey Kelley (b) (4)	06 Aug 2020 14:04:38
	(b) (4)	

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '18:40'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered '5 Aug 2020 18:40'	System	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '69'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'bpm'	System	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'breaths/min'	System	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '139'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'mmHg'	System	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '89'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'mmHg'	System	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:46:20
User closed query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:22:42
Query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' answered with 'DATA CORRECTION MADE' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 13:49:38
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 13:49:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4) (b) (4)	09 Oct 2020 13:49:33
User opened query 'Per CDM: Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well. Thanks.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:00:37
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	28 Sep 2020 16:57:29
User entered '158.8' cm	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	13 Oct 2020 13:46:20
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	09 Oct 2020 13:49:33
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Linden DeBoer (b) (4)	09 Oct 2020 13:49:33
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
	(b) (4)	
User entered '72.6' kg	Kelsey Kelley (b) (4)	06 Aug 2020 14:04:38
	(b) (4)	

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 06:55:04
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 min per protocol' (Site from System).	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:55
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		06 Aug 2020 14:04:38
User entered '20:30'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered '5 Aug 2020 20:30'	System	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '36.6' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '82'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'bpm'	System	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'breaths/min'	System	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '136'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'mmHg'	System	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:18
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '84'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'mmHg'	System	06 Aug 2020 14:04:38

US3032110

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 13:49:18

US3032110

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:45:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	06 Aug 2020 13:49:46
User entered '5 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	06 Aug 2020 13:49:46
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	06 Aug 2020 13:49:18
User entered '6 Aug 2020'	Kelsey Kelley (b) (4)	06 Aug 2020 13:49:18

US3032110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:46:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 01:05:51
	(b) (4)	

US3032110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:46:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:05:51

US3032110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

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)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:46:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:05:51

US3032110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 01:05:51

US3032110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:46:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:05:51

US3032110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:46:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '19:59'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:05:51

US3032110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered '5 Aug 2020 19:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:46:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 01:05:51

US3032110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:46:47
User entered 'ONCE'	System	06 Aug 2020 01:05:51

US3032110

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 01:05:51

US3032110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:46:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:05:32

US3032110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:46:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '5 Aug 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:05:32

US3032110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:46:54
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '19:14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:05:32

US3032110

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered '5 Aug 2020 19:14'	System	06 Aug 2020 14:05:32

US3032110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:46:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:47:07
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated (05AUG2020) sample recorded in EDC for Visit 1 Day 1, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' canceled (Site from DM).		20 Oct 2020 13:17:02
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated (05AUG2020) sample recorded in EDC for Visit 1 Day 1, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:24:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	06 Aug 2020 14:07:01
User entered '5 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	06 Aug 2020 14:07:01
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '6 Aug 2020'	System	06 Aug 2020 14:05:58
	Kelsey Kelley (b) (4)	06 Aug 2020 14:05:58

US3032110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kelsey Kelley (b) (4)	06 Aug 2020 14:05:58

US3032110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:47:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:05:58

US3032110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:47:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '18:57'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:05:58

US3032110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered '5 Aug 2020 18:57'	System	06 Aug 2020 14:07:01
User entered '6 Aug 2020 18:57'	System	06 Aug 2020 14:05:58

US3032110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kelsey Kelley (b) (4)	06 Aug 2020 14:05:58

US3032110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:47:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:05:58

US3032110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:47:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:05:58

US3032110

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered empty.	System	06 Aug 2020 14:05:58

US3032110

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:47:13
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:07:05

US3032110

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'I'	System	06 Aug 2020 14:07:05

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:32:06', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2c5248bd-ef86-48fd-909f-13a146f47fb1' User entered 'Yes (Y)'	System	06 Aug 2020 01:32:34
	System	06 Aug 2020 01:32:34

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:32:12', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2c5248bd-ef86-48fd-909f-13a146f47fb1' User entered '97.8'	System	06 Aug 2020 01:32:34
	System	06 Aug 2020 01:32:34

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:32:21', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2c5248bd-ef86-48fd-909f-13a146f47fb1'	System	06 Aug 2020 01:32:34
User entered 'No (N)'	System	06 Aug 2020 01:32:34

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:32:30', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2c5248bd-ef86-48fd-909f-13a146f47fb1' User entered '05 Aug 2020 20:32'	System	06 Aug 2020 01:32:34
	System	06 Aug 2020 01:32:34

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '05 Aug 2020 20:19'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '05 Aug 2020 22:49'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:44:21', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'c4e52d4b-d0d7-4e36-bc62-a13b9f4d5c86' User entered 'Yes (Y)'	System	06 Aug 2020 04:44:42
	System	06 Aug 2020 04:44:42

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:44:29', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'c4e52d4b-d0d7-4e36-bc62-a13b9f4d5c86' User entered '97.9'	System	06 Aug 2020 04:44:42
	System	06 Aug 2020 04:44:42

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:44:33', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'c4e52d4b-d0d7-4e36-bc62-a13b9f4d5c86' User entered 'No (N)'	System	06 Aug 2020 04:44:42
	System	06 Aug 2020 04:44:42

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:44:38', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'c4e52d4b-d0d7-4e36-bc62-a13b9f4d5c86'	System	06 Aug 2020 04:44:42
User entered '05 Aug 2020 23:44'	System	06 Aug 2020 04:44:42

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '05 Aug 2020 23:44'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '06 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 2'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:28:34', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '98778642-500d-4ed5-8eff-cb456840a19d' User entered 'Yes (Y)'	System	07 Aug 2020 01:29:06
	System	07 Aug 2020 01:29:06

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:28:47', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '98778642-500d-4ed5-8eff-cb456840a19d' User entered '98.3'	System	07 Aug 2020 01:29:06
	System	07 Aug 2020 01:29:06

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:28:59', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '98778642-500d-4ed5-8eff-cb456840a19d'	System	07 Aug 2020 01:29:06
User entered 'No (N)'	System	07 Aug 2020 01:29:06

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:29:04', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '98778642-500d-4ed5-8eff-cb456840a19d' User entered '06 Aug 2020 20:29'	System	07 Aug 2020 01:29:06
	System	07 Aug 2020 01:29:06

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 3'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:00:34', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '6ec380ca-7bbf-4c43-a867-4cf62c7ee562'	System	07 Aug 2020 17:00:53
User entered 'Yes (Y)'	System	07 Aug 2020 17:00:53

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:00:40', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '6ec380ca-7bbf-4c43-a867-4cf62c7ee562' User entered '97.9'	System	07 Aug 2020 17:00:53
	System	07 Aug 2020 17:00:53

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:00:45', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '6ec380ca-7bbf-4c43-a867-4cf62c7ee562'	System	07 Aug 2020 17:00:53
User entered 'No (N)'	System	07 Aug 2020 17:00:53

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:00:51', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '6ec380ca-7bbf-4c43-a867-4cf62c7ee562'	System	07 Aug 2020 17:00:53
User entered '07 Aug 2020 12:00'	System	07 Aug 2020 17:00:53

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 4'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:13:41', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '7baf0c37-63ba-4f13-bc1c-353b5cdefdec' User entered 'Yes (Y)'	System	09 Aug 2020 05:14:10
	System	09 Aug 2020 05:14:10

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:13:55', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '7baf0c37-63ba-4f13-bc1c-353b5cdefdec' User entered '97.8'	System	09 Aug 2020 05:14:10
	System	09 Aug 2020 05:14:10

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:13:59', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '7baf0c37-63ba-4f13-bc1c-353b5cdefdec'	System	09 Aug 2020 05:14:10
User entered 'No (N)'	System	09 Aug 2020 05:14:10

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:07', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '7baf0c37-63ba-4f13-bc1c-353b5cdefdec' User entered '09 Aug 2020 00:14'	System	09 Aug 2020 05:14:10
	System	09 Aug 2020 05:14:10

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 5'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T05:59:19', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'fe193edb-4f30-4106-94f2-0e6b85fed20d' User entered 'Yes (Y)'	System	10 Aug 2020 10:59:47
	System	10 Aug 2020 10:59:47

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T05:59:34', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'fe193edb-4f30-4106-94f2-0e6b85fed20d' User entered '98.2'	System	10 Aug 2020 10:59:47
	System	10 Aug 2020 10:59:47

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T05:59:38', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'fe193edb-4f30-4106-94f2-0e6b85fed20d' User entered 'No (N)'	System	10 Aug 2020 10:59:47
	System	10 Aug 2020 10:59:47

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T05:59:45', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'fe193edb-4f30-4106-94f2-0e6b85fed20d' User entered '10 Aug 2020 05:59'	System	10 Aug 2020 10:59:47
	System	10 Aug 2020 10:59:47

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 6'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T05:59:22', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'fd9fdd78-fbc3-4c82-8f63-742a8b716c44'	System	11 Aug 2020 10:59:54
User entered 'Yes (Y)'	System	11 Aug 2020 10:59:54

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T05:59:46', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'fd9fdd78-fbc3-4c82-8f63-742a8b716c44' User entered '96.9'	System	11 Aug 2020 10:59:54
	System	11 Aug 2020 10:59:54

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T05:59:41', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'fd9fdd78-fbc3-4c82-8f63-742a8b716c44'	System	11 Aug 2020 10:59:54
User entered 'No (N)'	System	11 Aug 2020 10:59:54

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T05:59:53', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'fd9fdd78-fbc3-4c82-8f63-742a8b716c44'	System	11 Aug 2020 10:59:54
User entered '11 Aug 2020 05:59'	System	11 Aug 2020 10:59:54

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 7'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:55:21', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'e100e146-7d52-46a9-842c-a4ff8d23b507'	System	12 Aug 2020 15:55:40
User entered 'Yes (Y)'	System	12 Aug 2020 15:55:40

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:55:31', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'e100e146-7d52-46a9-842c-a4ff8d23b507' User entered '96.5'	System	12 Aug 2020 15:55:40
	System	12 Aug 2020 15:55:40

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:55:35', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'e100e146-7d52-46a9-842c-a4ff8d23b507'	System	12 Aug 2020 15:55:40
User entered 'No (N)'	System	12 Aug 2020 15:55:40

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:55:37', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'e100e146-7d52-46a9-842c-a4ff8d23b507'	System	12 Aug 2020 15:55:40
User entered '12 Aug 2020 10:55'	System	12 Aug 2020 15:55:40

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:32:55', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4e0fed4c-9e54-43ce-b43d-a2fd2af8a22e'	System	06 Aug 2020 01:33:19
User entered 'None (1)'	System	06 Aug 2020 01:33:19

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:32:59', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4e0fed4c-9e54-43ce-b43d-a2fd2af8a22e' User entered 'No (N)'	System	06 Aug 2020 01:33:19
	System	06 Aug 2020 01:33:19

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:33:04', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4e0fed4c-9e54-43ce-b43d-a2fd2af8a22e'	System	06 Aug 2020 01:33:19
User entered 'No (N)'	System	06 Aug 2020 01:33:19

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:33:11', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4e0fed4c-9e54-43ce-b43d-a2fd2af8a22e'	System	06 Aug 2020 01:33:19
User entered 'None (1)'	System	06 Aug 2020 01:33:19

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:33:18', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4e0fed4c-9e54-43ce-b43d-a2fd2af8a22e'	System	06 Aug 2020 01:33:19
User entered '05 Aug 2020 20:33'	System	06 Aug 2020 01:33:19

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '05 Aug 2020 20:19'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '05 Aug 2020 22:49'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:44:49', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '040b24be-0634-4e15-8c89-d59a253d3c8a' User entered 'None (1)'	System	06 Aug 2020 04:45:27
	System	06 Aug 2020 04:45:27

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:44:53', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '040b24be-0634-4e15-8c89-d59a253d3c8a' User entered 'No (N)'	System	06 Aug 2020 04:45:27
	System	06 Aug 2020 04:45:27

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:45:14', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '040b24be-0634-4e15-8c89-d59a253d3c8a' User entered 'No (N)'	System	06 Aug 2020 04:45:27
	System	06 Aug 2020 04:45:27

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:45:18', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '040b24be-0634-4e15-8c89-d59a253d3c8a' User entered 'None (1)'	System	06 Aug 2020 04:45:27
	System	06 Aug 2020 04:45:27

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:45:25', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '040b24be-0634-4e15-8c89-d59a253d3c8a' User entered '05 Aug 2020 23:45'	System	06 Aug 2020 04:45:27
	System	06 Aug 2020 04:45:27

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '05 Aug 2020 23:44'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '06 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 2'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:29:31', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f9d2bbbd-01ec-4e15-be38-c5eb6dae156b' User entered 'None (1)'	System	07 Aug 2020 01:30:03
	System	07 Aug 2020 01:30:03

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:29:41', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f9d2bbbd-01ec-4e15-be38-c5eb6dae156b' User entered 'No (N)'	System	07 Aug 2020 01:30:03
	System	07 Aug 2020 01:30:03

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:29:44', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f9d2bbbd-01ec-4e15-be38-c5eb6dae156b' User entered 'No (N)'	System	07 Aug 2020 01:30:03
	System	07 Aug 2020 01:30:03

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:29:51', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f9d2bbbd-01ec-4e15-be38-c5eb6dae156b' User entered 'None (1)'	System	07 Aug 2020 01:30:03
	System	07 Aug 2020 01:30:03

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:30:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f9d2bbbd-01ec-4e15-be38-c5eb6dae156b' User entered '06 Aug 2020 20:30'	System	07 Aug 2020 01:30:03
	System	07 Aug 2020 01:30:03

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 3'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:00:57', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '46871654-53e0-4e0c-9f0e-3330b0707064' User entered 'None (1)'	System	07 Aug 2020 17:01:25
	System	07 Aug 2020 17:01:25

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:01:04', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '46871654-53e0-4e0c-9f0e-3330b0707064' User entered 'No (N)'	System	07 Aug 2020 17:01:25
	System	07 Aug 2020 17:01:25

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:01:08', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '46871654-53e0-4e0c-9f0e-3330b0707064' User entered 'No (N)'	System	07 Aug 2020 17:01:25
	System	07 Aug 2020 17:01:25

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:01:12', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '46871654-53e0-4e0c-9f0e-3330b0707064' User entered 'None (1)'	System	07 Aug 2020 17:01:25
	System	07 Aug 2020 17:01:25

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:01:20', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '46871654-53e0-4e0c-9f0e-3330b0707064' User entered '07 Aug 2020 12:01'	System	07 Aug 2020 17:01:25
	System	07 Aug 2020 17:01:25

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 4'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:12', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '101daadb-e0b2-481f-a5bb-75a0a05d9fd6' User entered 'None (1)'	System	09 Aug 2020 05:14:33
	System	09 Aug 2020 05:14:33

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:16', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '101daadb-e0b2-481f-a5bb-75a0a05d9fd6' User entered 'No (N)'	System	09 Aug 2020 05:14:33
	System	09 Aug 2020 05:14:33

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:22', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '101daadb-e0b2-481f-a5bb-75a0a05d9fd6' User entered 'No (N)'	System	09 Aug 2020 05:14:33
	System	09 Aug 2020 05:14:33

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:25', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '101daadb-e0b2-481f-a5bb-75a0a05d9fd6' User entered 'None (1)'	System	09 Aug 2020 05:14:33
	System	09 Aug 2020 05:14:33

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:29', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '101daadb-e0b2-481f-a5bb-75a0a05d9fd6' User entered '09 Aug 2020 00:14'	System	09 Aug 2020 05:14:33
	System	09 Aug 2020 05:14:33

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 5'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T05:59:50', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'a54b407e-9886-45cd-b811-64b0132f949d' User entered 'None (1)'	System	10 Aug 2020 11:00:20
	System	10 Aug 2020 11:00:20

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T06:00:02', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'a54b407e-9886-45cd-b811-64b0132f949d' User entered 'No (N)'	System	10 Aug 2020 11:00:20
	System	10 Aug 2020 11:00:20

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T06:00:08', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'a54b407e-9886-45cd-b811-64b0132f949d' User entered 'No (N)'	System	10 Aug 2020 11:00:20
	System	10 Aug 2020 11:00:20

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T06:00:13', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'a54b407e-9886-45cd-b811-64b0132f949d' User entered 'None (1)'	System	10 Aug 2020 11:00:20
	System	10 Aug 2020 11:00:20

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T06:00:19', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'a54b407e-9886-45cd-b811-64b0132f949d' User entered '10 Aug 2020 06:00'	System	10 Aug 2020 11:00:20
	System	10 Aug 2020 11:00:20

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 6'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T05:59:59', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f106a23d-0a7d-496b-98cc-29c8d3eaac52'	System	11 Aug 2020 11:00:19
User entered 'None (1)'	System	11 Aug 2020 11:00:19

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T06:00:03', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f106a23d-0a7d-496b-98cc-29c8d3eaac52'	System	11 Aug 2020 11:00:19
User entered 'No (N)'	System	11 Aug 2020 11:00:19

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T06:00:07', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f106a23d-0a7d-496b-98cc-29c8d3eaac52'	System	11 Aug 2020 11:00:19
User entered 'No (N)'	System	11 Aug 2020 11:00:19

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T06:00:11', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f106a23d-0a7d-496b-98cc-29c8d3eaac52' User entered 'None (1)'	System	11 Aug 2020 11:00:19
	System	11 Aug 2020 11:00:19

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T06:00:15', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f106a23d-0a7d-496b-98cc-29c8d3eaac52'	System	11 Aug 2020 11:00:19
User entered '11 Aug 2020 06:00'	System	11 Aug 2020 11:00:19

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 7'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:55:43', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1ca6f8a4-774a-49da-88ee-9dfb5683f5ad'	System	12 Aug 2020 15:55:56
User entered 'None (1)'	System	12 Aug 2020 15:55:56

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:55:46', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1ca6f8a4-774a-49da-88ee-9dfb5683f5ad'	System	12 Aug 2020 15:55:56
User entered 'No (N)'	System	12 Aug 2020 15:55:56

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:55:48', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1ca6f8a4-774a-49da-88ee-9dfb5683f5ad' User entered 'No (N)'	System	12 Aug 2020 15:55:56
	System	12 Aug 2020 15:55:56

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:55:51', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1ca6f8a4-774a-49da-88ee-9dfb5683f5ad' User entered 'None (1)'	System	12 Aug 2020 15:55:56
	System	12 Aug 2020 15:55:56

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:55:55', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1ca6f8a4-774a-49da-88ee-9dfb5683f5ad'	System	12 Aug 2020 15:55:56
User entered '12 Aug 2020 10:55'	System	12 Aug 2020 15:55:56

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:33:37', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f934f7b9-7c6a-4a78-9567-6551c727b489' User entered 'None (0)'	System	06 Aug 2020 01:34:16
	System	06 Aug 2020 01:34:16

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:33:43', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f934f7b9-7c6a-4a78-9567-6551c727b489' User entered 'None (0)'	System	06 Aug 2020 01:34:16
	System	06 Aug 2020 01:34:16

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:33:47', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f934f7b9-7c6a-4a78-9567-6551c727b489' User entered 'None (0)'	System	06 Aug 2020 01:34:16
	System	06 Aug 2020 01:34:16

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:33:51', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f934f7b9-7c6a-4a78-9567-6551c727b489' User entered 'None (0)'	System	06 Aug 2020 01:34:16
	System	06 Aug 2020 01:34:16

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:33:54', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f934f7b9-7c6a-4a78-9567-6551c727b489' User entered 'None (0)'	System	06 Aug 2020 01:34:16
	System	06 Aug 2020 01:34:16

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:33:57', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f934f7b9-7c6a-4a78-9567-6551c727b489' User entered 'None (0)'	System	06 Aug 2020 01:34:16
	System	06 Aug 2020 01:34:16

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:34:05', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f934f7b9-7c6a-4a78-9567-6551c727b489' User entered 'No (N)'	System	06 Aug 2020 01:34:16
	System	06 Aug 2020 01:34:16

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T20:34:12', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f934f7b9-7c6a-4a78-9567-6551c727b489' User entered '05 Aug 2020 20:34'	System	06 Aug 2020 01:34:16
	System	06 Aug 2020 01:34:16

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '05 Aug 2020 20:19'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '05 Aug 2020 22:49'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:45:34', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b8357ea-3ccc-45eb-9dff-02d911f9d4d3'	System	06 Aug 2020 04:46:31
User entered 'None (0)'	System	06 Aug 2020 04:46:31

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:45:39', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b8357ea-3ccc-45eb-9dff-02d911f9d4d3'	System	06 Aug 2020 04:46:31
User entered 'None (0)'	System	06 Aug 2020 04:46:31

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:45:45', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b8357ea-3ccc-45eb-9dff-02d911f9d4d3' User entered 'None (0)'	System	06 Aug 2020 04:46:31
	System	06 Aug 2020 04:46:31

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:45:59', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b8357ea-3ccc-45eb-9dff-02d911f9d4d3'	System	06 Aug 2020 04:46:31
User entered 'None (0)'	System	06 Aug 2020 04:46:31

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:46:05', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b8357ea-3ccc-45eb-9dff-02d911f9d4d3'	System	06 Aug 2020 04:46:31
User entered 'None (0)'	System	06 Aug 2020 04:46:31

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:46:13', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b8357ea-3ccc-45eb-9dff-02d911f9d4d3' User entered 'None (0)'	System	06 Aug 2020 04:46:31
	System	06 Aug 2020 04:46:31

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:46:20', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b8357ea-3ccc-45eb-9dff-02d911f9d4d3'	System	06 Aug 2020 04:46:31
User entered 'No (N)'	System	06 Aug 2020 04:46:31

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-05T23:46:27', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b8357ea-3ccc-45eb-9dff-02d911f9d4d3'	System	06 Aug 2020 04:46:31
User entered '05 Aug 2020 23:46'	System	06 Aug 2020 04:46:31

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '05 Aug 2020 23:44'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '06 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 2'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:30:11', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b798a908-4b74-41df-b0e0-3433ec8cdfe0' User entered 'None (0)'	System	07 Aug 2020 01:31:10
	System	07 Aug 2020 01:31:10

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:30:17', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b798a908-4b74-41df-b0e0-3433ec8cdfe0' User entered 'None (0)'	System	07 Aug 2020 01:31:10
	System	07 Aug 2020 01:31:10

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:30:22', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b798a908-4b74-41df-b0e0-3433ec8cdf0'	System	07 Aug 2020 01:31:10
User entered 'None (0)'	System	07 Aug 2020 01:31:10

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:30:29', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b798a908-4b74-41df-b0e0-3433ec8cdf0'	System	07 Aug 2020 01:31:10
User entered 'None (0)'	System	07 Aug 2020 01:31:10

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:30:39', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b798a908-4b74-41df-b0e0-3433ec8cdfe0' User entered 'None (0)'	System	07 Aug 2020 01:31:10
	System	07 Aug 2020 01:31:10

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:30:42', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b798a908-4b74-41df-b0e0-3433ec8cdfe0' User entered 'None (0)'	System	07 Aug 2020 01:31:10
	System	07 Aug 2020 01:31:10

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:30:54', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b798a908-4b74-41df-b0e0-3433ec8cdf0'	System	07 Aug 2020 01:31:10
User entered 'No (N)'	System	07 Aug 2020 01:31:10

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-06T20:31:03', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b798a908-4b74-41df-b0e0-3433ec8cdfe0' User entered '06 Aug 2020 20:31'	System	07 Aug 2020 01:31:10
	System	07 Aug 2020 01:31:10

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 3'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:01:28', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '5625bd0f-8a68-48d8-8c01-2e28981aa519' User entered 'None (0)'	System	07 Aug 2020 17:02:04
	System	07 Aug 2020 17:02:04

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:01:31', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '5625bd0f-8a68-48d8-8c01-2e28981aa519' User entered 'None (0)'	System	07 Aug 2020 17:02:04
	System	07 Aug 2020 17:02:04

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:01:34', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '5625bd0f-8a68-48d8-8c01-2e28981aa519' User entered 'None (0)'	System	07 Aug 2020 17:02:04
	System	07 Aug 2020 17:02:04

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:01:37', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '5625bd0f-8a68-48d8-8c01-2e28981aa519' User entered 'None (0)'	System	07 Aug 2020 17:02:04
	System	07 Aug 2020 17:02:04

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:01:40', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '5625bd0f-8a68-48d8-8c01-2e28981aa519' User entered 'None (0)'	System	07 Aug 2020 17:02:04
	System	07 Aug 2020 17:02:04

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:01:42', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '5625bd0f-8a68-48d8-8c01-2e28981aa519' User entered 'None (0)'	System	07 Aug 2020 17:02:04
	System	07 Aug 2020 17:02:04

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:01:49', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '5625bd0f-8a68-48d8-8c01-2e28981aa519' User entered 'No (N)'	System	07 Aug 2020 17:02:04
	System	07 Aug 2020 17:02:04

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-07T12:02:01', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '5625bd0f-8a68-48d8-8c01-2e28981aa519' User entered '07 Aug 2020 12:02'	System	07 Aug 2020 17:02:04
	System	07 Aug 2020 17:02:04

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 4'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:36', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60bbcfad-7f37-4bc8-8c4e-d2da1d0d24a0' User entered 'None (0)'	System	09 Aug 2020 05:15:11
	System	09 Aug 2020 05:15:11

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:38', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60bbcfad-7f37-4bc8-8c4e-d2da1d0d24a0' User entered 'None (0)'	System	09 Aug 2020 05:15:11
	System	09 Aug 2020 05:15:11

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:46', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60bbcfad-7f37-4bc8-8c4e-d2da1d0d24a0' User entered 'None (0)'	System	09 Aug 2020 05:15:11
	System	09 Aug 2020 05:15:11

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:51', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60bbcfad-7f37-4bc8-8c4e-d2da1d0d24a0' User entered 'None (0)'	System	09 Aug 2020 05:15:11
	System	09 Aug 2020 05:15:11

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:53', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60bbcfad-7f37-4bc8-8c4e-d2da1d0d24a0' User entered 'None (0)'	System	09 Aug 2020 05:15:11
	System	09 Aug 2020 05:15:11

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:56', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60bbcfad-7f37-4bc8-8c4e-d2da1d0d24a0' User entered 'None (0)'	System	09 Aug 2020 05:15:11
	System	09 Aug 2020 05:15:11

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:14:59', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60bbcfad-7f37-4bc8-8c4e-d2da1d0d24a0' User entered 'No (N)'	System	09 Aug 2020 05:15:11
	System	09 Aug 2020 05:15:11

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-09T00:15:07', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60bbcfad-7f37-4bc8-8c4e-d2da1d0d24a0' User entered '09 Aug 2020 00:15'	System	09 Aug 2020 05:15:11
	System	09 Aug 2020 05:15:11

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 5'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T06:00:27', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4500702d-656b-4498-a632-88fc35d2751a' User entered 'None (0)'	System	10 Aug 2020 11:00:55
	System	10 Aug 2020 11:00:55

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T06:00:30', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4500702d-656b-4498-a632-88fc35d2751a' User entered 'None (0)'	System	10 Aug 2020 11:00:55
	System	10 Aug 2020 11:00:55

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T06:00:32', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4500702d-656b-4498-a632-88fc35d2751a' User entered 'None (0)'	System	10 Aug 2020 11:00:55
	System	10 Aug 2020 11:00:55

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T06:00:35', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4500702d-656b-4498-a632-88fc35d2751a' User entered 'None (0)'	System	10 Aug 2020 11:00:55
	System	10 Aug 2020 11:00:55

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T06:00:37', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4500702d-656b-4498-a632-88fc35d2751a' User entered 'None (0)'	System	10 Aug 2020 11:00:55
	System	10 Aug 2020 11:00:55

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T06:00:40', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4500702d-656b-4498-a632-88fc35d2751a' User entered 'None (0)'	System	10 Aug 2020 11:00:55
	System	10 Aug 2020 11:00:55

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T06:00:44', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4500702d-656b-4498-a632-88fc35d2751a' User entered 'No (N)'	System	10 Aug 2020 11:00:55
	System	10 Aug 2020 11:00:55

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-10T06:00:52', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4500702d-656b-4498-a632-88fc35d2751a' User entered '10 Aug 2020 06:00'	System	10 Aug 2020 11:00:55
	System	10 Aug 2020 11:00:55

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 6'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T06:00:22', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'ae953763-d362-4bca-a22d-fe971696f5bc' User entered 'None (0)'	System	11 Aug 2020 11:00:50
	System	11 Aug 2020 11:00:50

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T06:00:24', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'ae953763-d362-4bca-a22d-fe971696f5bc'	System	11 Aug 2020 11:00:50
User entered 'None (0)'	System	11 Aug 2020 11:00:50

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T06:00:28', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'ae953763-d362-4bca-a22d-fe971696f5bc' User entered 'None (0)'	System	11 Aug 2020 11:00:50
	System	11 Aug 2020 11:00:50

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T06:00:32', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'ae953763-d362-4bca-a22d-fe971696f5bc'	System	11 Aug 2020 11:00:50
User entered 'None (0)'	System	11 Aug 2020 11:00:50

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T06:00:35', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'ae953763-d362-4bca-a22d-fe971696f5bc' User entered 'None (0)'	System	11 Aug 2020 11:00:50
	System	11 Aug 2020 11:00:50

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T06:00:38', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'ae953763-d362-4bca-a22d-fe971696f5bc' User entered 'None (0)'	System	11 Aug 2020 11:00:50
	System	11 Aug 2020 11:00:50

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T06:00:43', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'ae953763-d362-4bca-a22d-fe971696f5bc'	System	11 Aug 2020 11:00:50
User entered 'No (N)'	System	11 Aug 2020 11:00:50

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-11T06:00:46', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'ae953763-d362-4bca-a22d-fe971696f5bc'	System	11 Aug 2020 11:00:50
User entered '11 Aug 2020 06:00'	System	11 Aug 2020 11:00:50

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 7'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:55:59', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'e4f1dcb0-af00-48c7-a6bb-45b444bc50df' User entered 'None (0)'	System	12 Aug 2020 15:56:23
	System	12 Aug 2020 15:56:23

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:56:01', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'e4f1dcb0-af00-48c7-a6bb-45b444bc50df' User entered 'None (0)'	System	12 Aug 2020 15:56:23
	System	12 Aug 2020 15:56:23

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:56:03', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'e4f1dcb0-af00-48c7-a6bb-45b444bc50df' User entered 'None (0)'	System	12 Aug 2020 15:56:23
	System	12 Aug 2020 15:56:23

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:56:08', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'e4f1dcb0-af00-48c7-a6bb-45b444bc50df' User entered 'None (0)'	System	12 Aug 2020 15:56:23
	System	12 Aug 2020 15:56:23

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:56:11', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'e4f1dcb0-af00-48c7-a6bb-45b444bc50df' User entered 'None (0)'	System	12 Aug 2020 15:56:23
	System	12 Aug 2020 15:56:23

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:56:13', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'e4f1dcb0-af00-48c7-a6bb-45b444bc50df' User entered 'None (0)'	System	12 Aug 2020 15:56:23
	System	12 Aug 2020 15:56:23

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:56:18', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'e4f1dcb0-af00-48c7-a6bb-45b444bc50df' User entered 'No (N)'	System	12 Aug 2020 15:56:23
	System	12 Aug 2020 15:56:23

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-08-12T10:56:20', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'e4f1dcb0-af00-48c7-a6bb-45b444bc50df' User entered '12 Aug 2020 10:56'	System	12 Aug 2020 15:56:23
	System	12 Aug 2020 15:56:23

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 01:05:51

US3032110

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:47:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4)	
	Samantha Wieseler (b) (4)	20 Aug 2020 02:51:30
	(b) (4)	

US3032110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:47:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '14 Aug 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 02:51:30

US3032110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:47:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 02:51:30

US3032110

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:47:40
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4)	
	Samantha Wieseler (b) (4)	20 Aug 2020 02:51:30
	(b) (4)	

US3032110

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:47:43
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4)	
	Samantha Wieseler (b) (4)	20 Aug 2020 02:51:34
	(b) (4)	

US3032110

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'I'	System	20 Aug 2020 02:51:34

US3032110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:48:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 02:51:48

US3032110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:48:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '19 Aug 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 02:51:48

US3032110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:48:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 02:51:48

US3032110

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:48:22
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 02:51:48

US3032110

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
DataPoint Verified.		26 Feb 2021 01:48:25
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	20 Aug 2020 02:51:52

US3032110

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:01:33
User entered 'I'	System	20 Aug 2020 02:51:52

US3032110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:00
DataPoint Verified.		26 Feb 2021 01:49:26
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 20:22:39

US3032110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:00
DataPoint Verified.		26 Feb 2021 01:49:26
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
	System	29 Sep 2020 20:22:56
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	29 Sep 2020 20:22:56
User entered '26 Aug 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	29 Sep 2020 20:22:56
	(b) (4)	
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Sep 2020 20:22:39
User entered '19 Aug 2020'	Kelsey Kelley (b) (4)	29 Sep 2020 20:22:39
	(b) (4)	

US3032110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:00
DataPoint Verified.		26 Feb 2021 01:49:26
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 20:22:39

US3032110

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:00
DataPoint Verified.		26 Feb 2021 01:49:26
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 20:22:39

US3032110

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:00
DataPoint Verified.		26 Feb 2021 01:49:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 21:15:29

US3032110

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:19:00
User entered 'I'	System	08 Sep 2020 21:15:29

US3032110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:27
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:05:51

US3032110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:27
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '8 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:05:51

US3032110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

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 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:27
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	System	08 Sep 2020 23:05:54
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	Linden DeBoer (b) (4)	08 Sep 2020 23:05:54
User entered empty.	(b) (4)	
	System	08 Sep 2020 23:05:51
	Linden DeBoer (b) (4)	08 Sep 2020 23:05:51
	(b) (4)	

US3032110

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'VISIT2'	System	08 Sep 2020 23:05:51

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User accepted default value 'Pre-Dose (PREDOSE)'	Linden DeBoer (b) (4)	08 Sep 2020 23:08:11
	(b) (4)	

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '8 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '14:59'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '8 Sep 2020 14:59'	System	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '36.8' C	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '84'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'bpm'	System	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '16'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'breaths/min'	System	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '138'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'mmHg'	System	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '90'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'mmHg'	System	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User accepted default value 'Post-Dose (POSTDOSE)'	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '8 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '16:40'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '8 Sep 2020 16:40'	System	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '36.6' C	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Oral (Oral)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4)	
	Linden DeBoer (b) (4)	08 Sep 2020 23:08:11
	(b) (4)	

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '66'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'bpm'	System	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '14'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'breaths/min'	System	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '136'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'mmHg'	System	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:50:31
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '76'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'mmHg'	System	08 Sep 2020 23:08:11

US3032110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:52:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:16

US3032110

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:52:10
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '8 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:16

US3032110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 21:15:58

US3032110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 21:15:58

US3032110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

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 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 21:15:58

US3032110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 21:15:58

US3032110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 21:15:58

US3032110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '16:03'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 21:15:58

US3032110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '08 Sep 2020 16:03'	System	08 Sep 2020 21:15:58

US3032110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:08
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 21:15:58

US3032110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:08
User entered 'ONCE'	System	08 Sep 2020 21:15:58

US3032110

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 21:15:58

US3032110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:38

US3032110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '8 Sep 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:38

US3032110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:39
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '15:32'	(b) (4)	
	Linden DeBoer (b) (4)	08 Sep 2020 23:08:38
	(b) (4)	

US3032110

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '8 Sep 2020 15:32'	System	08 Sep 2020 23:08:38

US3032110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:46:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:59
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated(08SEP2020) sample recorded in EDC for Visit 2 Day 29, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' canceled (Site from DM).		20 Oct 2020 13:17:07
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Central Laboratory - Nasopharyngeal Swab dated(08SEP2020) sample recorded in EDC for Visit 2 Day 29, however same is missing in PPD Central lab. Please reconcile the sample and provide the tracking number if already shipped. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:39:37
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '8 Sep 2020'	(b) (4) Linden DeBoer (b) (4)	08 Sep 2020 23:08:50

US3032110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:50

US3032110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:50

US3032110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '15:17'	(b) (4)	
	Linden DeBoer (b) (4)	08 Sep 2020 23:08:50
	(b) (4)	

US3032110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '8 Sep 2020 15:17'	System	08 Sep 2020 23:08:50

US3032110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:50

US3032110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:50

US3032110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:53:59
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:50

US3032110

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered empty.	System	08 Sep 2020 23:08:50

US3032110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:54:03
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	08 Sep 2020 23:08:55

US3032110

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '1'	System	08 Sep 2020 23:08:55

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:38:13', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2ade7973-27e8-400c-a9c7-86b235fd64a8' User entered 'Yes (Y)'	System	08 Sep 2020 21:38:38
	System	08 Sep 2020 21:38:38

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:38:19', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2ade7973-27e8-400c-a9c7-86b235fd64a8' User entered '97.9'	System	08 Sep 2020 21:38:38
	System	08 Sep 2020 21:38:38

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:38:28', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2ade7973-27e8-400c-a9c7-86b235fd64a8'	System	08 Sep 2020 21:38:38
User entered 'No (N)'	System	08 Sep 2020 21:38:38

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:38:34', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2ade7973-27e8-400c-a9c7-86b235fd64a8' User entered '08 Sep 2020 16:38'	System	08 Sep 2020 21:38:38
	System	08 Sep 2020 21:38:38

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Sep 2020 16:23'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Sep 2020 18:53'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:48:35', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'c55060c3-c854-4278-b626-14ad2ffb0d37'	System	09 Sep 2020 00:49:06
User entered 'Yes (Y)'	System	09 Sep 2020 00:49:06

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:48:42', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'c55060c3-c854-4278-b626-14ad2ffb0d37' User entered '98.4'	System	09 Sep 2020 00:49:06
	System	09 Sep 2020 00:49:06

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:48:47', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'c55060c3-c854-4278-b626-14ad2ffb0d37'	System	09 Sep 2020 00:49:06
User entered 'No (N)'	System	09 Sep 2020 00:49:06

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:49:02', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'c55060c3-c854-4278-b626-14ad2ffb0d37'	System	09 Sep 2020 00:49:06
User entered '08 Sep 2020 19:49'	System	09 Sep 2020 00:49:06

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Sep 2020 19:48'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 2'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:25:57', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '074a6c46-7676-4e09-9df4-0ab8519f41e2' User entered 'Yes (Y)'	System	10 Sep 2020 04:26:15
	System	10 Sep 2020 04:26:15

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:26:03', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '074a6c46-7676-4e09-9df4-0ab8519f41e2' User entered '97.8'	System	10 Sep 2020 04:26:15
	System	10 Sep 2020 04:26:15

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:26:07', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '074a6c46-7676-4e09-9df4-0ab8519f41e2'	System	10 Sep 2020 04:26:15
User entered 'No (N)'	System	10 Sep 2020 04:26:15

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:26:12', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '074a6c46-7676-4e09-9df4-0ab8519f41e2'	System	10 Sep 2020 04:26:15
User entered '09 Sep 2020 23:26'	System	10 Sep 2020 04:26:15

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 3'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:49:42', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1517b3a4-9ece-43c7-be9b-a5887e1507d5' User entered 'Yes (Y)'	System	11 Sep 2020 14:50:05
	System	11 Sep 2020 14:50:05

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:49:51', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1517b3a4-9ece-43c7-be9b-a5887e1507d5' User entered '97.4'	System	11 Sep 2020 14:50:05
	System	11 Sep 2020 14:50:05

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:49:56', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1517b3a4-9ece-43c7-be9b-a5887e1507d5'	System	11 Sep 2020 14:50:05
User entered 'No (N)'	System	11 Sep 2020 14:50:05

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:50:02', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1517b3a4-9ece-43c7-be9b-a5887e1507d5' User entered '11 Sep 2020 09:50'	System	11 Sep 2020 14:50:05
	System	11 Sep 2020 14:50:05

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 4'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:37:54', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '9565a20f-75ae-45e3-800e-12ab2edb41b1' User entered 'Yes (Y)'	System	12 Sep 2020 04:38:16
	System	12 Sep 2020 04:38:16

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:38:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '9565a20f-75ae-45e3-800e-12ab2edb41b1' User entered '98.4'	System	12 Sep 2020 04:38:16
	System	12 Sep 2020 04:38:16

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:38:04', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '9565a20f-75ae-45e3-800e-12ab2edb41b1' User entered 'No (N)'	System	12 Sep 2020 04:38:16
	System	12 Sep 2020 04:38:16

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:38:14', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '9565a20f-75ae-45e3-800e-12ab2edb41b1' User entered '11 Sep 2020 23:38'	System	12 Sep 2020 04:38:16
	System	12 Sep 2020 04:38:16

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 5'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:52:29', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2ec5043b-ed16-40b5-bd0c-c630417ee883' User entered 'Yes (Y)'	System	13 Sep 2020 04:53:00
	System	13 Sep 2020 04:53:00

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:52:41', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2ec5043b-ed16-40b5-bd0c-c630417ee883' User entered '98.8'	System	13 Sep 2020 04:53:00
	System	13 Sep 2020 04:53:00

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:52:46', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2ec5043b-ed16-40b5-bd0c-c630417ee883' User entered 'No (N)'	System	13 Sep 2020 04:53:00
	System	13 Sep 2020 04:53:00

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:52:55', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2ec5043b-ed16-40b5-bd0c-c630417ee883' User entered '12 Sep 2020 23:52'	System	13 Sep 2020 04:53:00
	System	13 Sep 2020 04:53:00

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 6'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:40:52', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'bccab9d6-a2f3-43a7-ada2-cac2e125d0ec' User entered 'Yes (Y)'	System	14 Sep 2020 03:41:11
	System	14 Sep 2020 03:41:11

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:40:58', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'bccab9d6-a2f3-43a7-ada2-cac2e125d0ec' User entered '97.9'	System	14 Sep 2020 03:41:11
	System	14 Sep 2020 03:41:11

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:03', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'bccab9d6-a2f3-43a7-ada2-cac2e125d0ec' User entered 'No (N)'	System	14 Sep 2020 03:41:11
	System	14 Sep 2020 03:41:11

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:07', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'bccab9d6-a2f3-43a7-ada2-cac2e125d0ec' User entered '13 Sep 2020 22:41'	System	14 Sep 2020 03:41:11
	System	14 Sep 2020 03:41:11

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 7'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:11:42', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '19a7dfcc-5b20-43e9-815c-f157346317eb' User entered 'Yes (Y)'	System	15 Sep 2020 05:12:04
	System	15 Sep 2020 05:12:04

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:11:49', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '19a7dfcc-5b20-43e9-815c-f157346317eb' User entered '98.6'	System	15 Sep 2020 05:12:04
	System	15 Sep 2020 05:12:04

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:11:54', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '19a7dfcc-5b20-43e9-815c-f157346317eb' User entered 'No (N)'	System	15 Sep 2020 05:12:04
	System	15 Sep 2020 05:12:04

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:01', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '19a7dfcc-5b20-43e9-815c-f157346317eb' User entered '15 Sep 2020 00:12'	System	15 Sep 2020 05:12:04
	System	15 Sep 2020 05:12:04

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:38:39', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b54e72a6-3b1b-4822-b305-0a45e61a0f6f' User entered 'None (1)'	System	08 Sep 2020 21:39:07
	System	08 Sep 2020 21:39:07

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:38:51', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b54e72a6-3b1b-4822-b305-0a45e61a0f6f' User entered 'No (N)'	System	08 Sep 2020 21:39:07
	System	08 Sep 2020 21:39:07

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:38:55', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b54e72a6-3b1b-4822-b305-0a45e61a0f6f' User entered 'No (N)'	System	08 Sep 2020 21:39:07
	System	08 Sep 2020 21:39:07

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:39:01', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b54e72a6-3b1b-4822-b305-0a45e61a0f6f' User entered 'None (1)'	System	08 Sep 2020 21:39:07
	System	08 Sep 2020 21:39:07

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:39:04', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'b54e72a6-3b1b-4822-b305-0a45e61a0f6f' User entered '08 Sep 2020 16:39'	System	08 Sep 2020 21:39:07
	System	08 Sep 2020 21:39:07

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Sep 2020 16:23'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Sep 2020 18:53'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:49:17', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f5acf0f5-ffe0-4469-b43c-9bbc4d175ab0'	System	09 Sep 2020 00:49:50
User entered 'None (1)'	System	09 Sep 2020 00:49:50

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:49:23', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f5acf0f5-ffe0-4469-b43c-9bbc4d175ab0'	System	09 Sep 2020 00:49:50
User entered 'No (N)'	System	09 Sep 2020 00:49:50

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:49:30', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f5acf0f5-ffe0-4469-b43c-9bbc4d175ab0' User entered 'No (N)'	System	09 Sep 2020 00:49:50
	System	09 Sep 2020 00:49:50

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:49:34', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f5acf0f5-ffe0-4469-b43c-9bbc4d175ab0'	System	09 Sep 2020 00:49:50
User entered 'None (1)'	System	09 Sep 2020 00:49:50

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:49:48', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f5acf0f5-ffe0-4469-b43c-9bbc4d175ab0'	System	09 Sep 2020 00:49:50
User entered '08 Sep 2020 19:49'	System	09 Sep 2020 00:49:50

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Sep 2020 19:48'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 2'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:26:22', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3b281f8f-60f9-4053-943b-ba5043da994a' User entered 'None (1)'	System	10 Sep 2020 04:27:05
	System	10 Sep 2020 04:27:05

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:26:26', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3b281f8f-60f9-4053-943b-ba5043da994a' User entered 'No (N)'	System	10 Sep 2020 04:27:05
	System	10 Sep 2020 04:27:05

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:26:30', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3b281f8f-60f9-4053-943b-ba5043da994a' User entered 'No (N)'	System	10 Sep 2020 04:27:05
	System	10 Sep 2020 04:27:05

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:26:34', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3b281f8f-60f9-4053-943b-ba5043da994a' User entered 'None (1)'	System	10 Sep 2020 04:27:05
	System	10 Sep 2020 04:27:05

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:27:02', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3b281f8f-60f9-4053-943b-ba5043da994a' User entered '09 Sep 2020 23:27'	System	10 Sep 2020 04:27:05
	System	10 Sep 2020 04:27:05

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 3'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:50:10', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '50c599d6-3168-4f3c-a92a-44db10a9dfee'	System	11 Sep 2020 14:50:54
User entered 'None (1)'	System	11 Sep 2020 14:50:54

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:50:14', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '50c599d6-3168-4f3c-a92a-44db10a9dfee' User entered 'No (N)'	System	11 Sep 2020 14:50:54
	System	11 Sep 2020 14:50:54

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:50:18', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '50c599d6-3168-4f3c-a92a-44db10a9dfee' User entered 'No (N)'	System	11 Sep 2020 14:50:54
	System	11 Sep 2020 14:50:54

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:50:25', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '50c599d6-3168-4f3c-a92a-44db10a9dfee' User entered 'None (1)'	System	11 Sep 2020 14:50:54
	System	11 Sep 2020 14:50:54

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:50:51', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '50c599d6-3168-4f3c-a92a-44db10a9dfee' User entered '11 Sep 2020 09:50'	System	11 Sep 2020 14:50:54
	System	11 Sep 2020 14:50:54

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 4'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:38:24', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1294b49e-02c5-420b-9957-ffe9c250fcb9'	System	12 Sep 2020 04:38:59
User entered 'None (1)'	System	12 Sep 2020 04:38:59

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:38:29', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1294b49e-02c5-420b-9957-ffe9c250fcb9'	System	12 Sep 2020 04:38:59
User entered 'No (N)'	System	12 Sep 2020 04:38:59

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:38:35', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1294b49e-02c5-420b-9957-ffe9c250fcb9'	System	12 Sep 2020 04:38:59
User entered 'No (N)'	System	12 Sep 2020 04:38:59

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:38:42', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1294b49e-02c5-420b-9957-ffe9c250fcb9'	System	12 Sep 2020 04:38:59
User entered 'None (1)'	System	12 Sep 2020 04:38:59

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:38:57', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1294b49e-02c5-420b-9957-ffebe250fcb9'	System	12 Sep 2020 04:38:59
User entered '11 Sep 2020 23:38'	System	12 Sep 2020 04:38:59

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 5'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:53:03', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '854d56fa-3765-497b-83d7-305e4c29e9a9' User entered 'None (1)'	System	13 Sep 2020 04:53:31
	System	13 Sep 2020 04:53:31

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:53:16', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '854d56fa-3765-497b-83d7-305e4c29e9a9' User entered 'No (N)'	System	13 Sep 2020 04:53:31
	System	13 Sep 2020 04:53:31

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:53:20', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '854d56fa-3765-497b-83d7-305e4c29e9a9' User entered 'No (N)'	System	13 Sep 2020 04:53:31
	System	13 Sep 2020 04:53:31

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:53:24', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '854d56fa-3765-497b-83d7-305e4c29e9a9' User entered 'None (1)'	System	13 Sep 2020 04:53:31
	System	13 Sep 2020 04:53:31

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:53:29', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '854d56fa-3765-497b-83d7-305e4c29e9a9' User entered '12 Sep 2020 23:53'	System	13 Sep 2020 04:53:31
	System	13 Sep 2020 04:53:31

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 6'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:17', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f3cfee23-5a4d-4718-a7db-6cbcc376d17a'	System	14 Sep 2020 03:41:40
User entered 'None (1)'	System	14 Sep 2020 03:41:40

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:21', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f3cfee23-5a4d-4718-a7db-6cbcc376d17a' User entered 'No (N)'	System	14 Sep 2020 03:41:40
	System	14 Sep 2020 03:41:40

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:26', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f3cfee23-5a4d-4718-a7db-6cbcc376d17a' User entered 'No (N)'	System	14 Sep 2020 03:41:40
	System	14 Sep 2020 03:41:40

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:29', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f3cfee23-5a4d-4718-a7db-6cbcc376d17a' User entered 'None (1)'	System	14 Sep 2020 03:41:40
	System	14 Sep 2020 03:41:40

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:37', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f3cfee23-5a4d-4718-a7db-6cbcc376d17a' User entered '13 Sep 2020 22:41'	System	14 Sep 2020 03:41:40
	System	14 Sep 2020 03:41:40

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 7'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:07', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '27fe144e-63f9-4677-8fed-ccc4ed01dd12'	System	15 Sep 2020 05:12:25
User entered 'None (1)'	System	15 Sep 2020 05:12:25

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:10', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '27fe144e-63f9-4677-8fed-ccc4ed01dd12' User entered 'No (N)'	System	15 Sep 2020 05:12:25
	System	15 Sep 2020 05:12:25

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:13', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '27fe144e-63f9-4677-8fed-ccc4ed01dd12'	System	15 Sep 2020 05:12:25
User entered 'No (N)'	System	15 Sep 2020 05:12:25

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:17', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '27fe144e-63f9-4677-8fed-ccc4ed01dd12'	System	15 Sep 2020 05:12:25
User entered 'None (1)'	System	15 Sep 2020 05:12:25

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:22', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '27fe144e-63f9-4677-8fed-ccc4ed01dd12'	System	15 Sep 2020 05:12:25
User entered '15 Sep 2020 00:12'	System	15 Sep 2020 05:12:25

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:39:09', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2d6abf14-365e-4645-ac1c-1d9c310c7947' User entered 'None (0)'	System	08 Sep 2020 21:39:32
	System	08 Sep 2020 21:39:32

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:39:12', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2d6abf14-365e-4645-ac1c-1d9c310c7947' User entered 'None (0)'	System	08 Sep 2020 21:39:32
	System	08 Sep 2020 21:39:32

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:39:15', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2d6abf14-365e-4645-ac1c-1d9c310c7947' User entered 'None (0)'	System	08 Sep 2020 21:39:32
	System	08 Sep 2020 21:39:32

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:39:18', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2d6abf14-365e-4645-ac1c-1d9c310c7947' User entered 'None (0)'	System	08 Sep 2020 21:39:32
	System	08 Sep 2020 21:39:32

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:39:21', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2d6abf14-365e-4645-ac1c-1d9c310c7947' User entered 'None (0)'	System	08 Sep 2020 21:39:32
	System	08 Sep 2020 21:39:32

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:39:23', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2d6abf14-365e-4645-ac1c-1d9c310c7947' User entered 'None (0)'	System	08 Sep 2020 21:39:32
	System	08 Sep 2020 21:39:32

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:39:26', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2d6abf14-365e-4645-ac1c-1d9c310c7947'	System	08 Sep 2020 21:39:32
User entered 'No (N)'	System	08 Sep 2020 21:39:32

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T16:39:29', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '2d6abf14-365e-4645-ac1c-1d9c310c7947'	System	08 Sep 2020 21:39:32
User entered '08 Sep 2020 16:39'	System	08 Sep 2020 21:39:32

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Sep 2020 16:23'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Sep 2020 18:53'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:49:53', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3327277e-fde0-4034-a7a1-d308cf091d08' User entered 'None (0)'	System	09 Sep 2020 00:50:36
	System	09 Sep 2020 00:50:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:49:56', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3327277e-fde0-4034-a7a1-d308cf091d08' User entered 'None (0)'	System	09 Sep 2020 00:50:36
	System	09 Sep 2020 00:50:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:50:01', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3327277e-fde0-4034-a7a1-d308cf091d08' User entered 'None (0)'	System	09 Sep 2020 00:50:36
	System	09 Sep 2020 00:50:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:50:06', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3327277e-fde0-4034-a7a1-d308cf091d08' User entered 'None (0)'	System	09 Sep 2020 00:50:36
	System	09 Sep 2020 00:50:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:50:08', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3327277e-fde0-4034-a7a1-d308cf091d08' User entered 'None (0)'	System	09 Sep 2020 00:50:36
	System	09 Sep 2020 00:50:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:50:11', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3327277e-fde0-4034-a7a1-d308cf091d08' User entered 'None (0)'	System	09 Sep 2020 00:50:36
	System	09 Sep 2020 00:50:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:50:24', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3327277e-fde0-4034-a7a1-d308cf091d08'	System	09 Sep 2020 00:50:36
User entered 'No (N)'	System	09 Sep 2020 00:50:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-08T19:50:30', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3327277e-fde0-4034-a7a1-d308cf091d08' User entered '08 Sep 2020 19:50'	System	09 Sep 2020 00:50:36
	System	09 Sep 2020 00:50:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '08 Sep 2020 19:48'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 2'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:27:07', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'aac68ae4-82e3-4ec7-aef8-1a92430c2fc9' User entered 'None (0)'	System	10 Sep 2020 04:32:23
	System	10 Sep 2020 04:32:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:27:09', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'aac68ae4-82e3-4ec7-aef8-1a92430c2fc9' User entered 'None (0)'	System	10 Sep 2020 04:32:23
	System	10 Sep 2020 04:32:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:27:12', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'aac68ae4-82e3-4ec7-aef8-1a92430c2fc9' User entered 'None (0)'	System	10 Sep 2020 04:32:23
	System	10 Sep 2020 04:32:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:27:14', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'aac68ae4-82e3-4ec7-aef8-1a92430c2fc9' User entered 'None (0)'	System	10 Sep 2020 04:32:23
	System	10 Sep 2020 04:32:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:27:16', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'aac68ae4-82e3-4ec7-aef8-1a92430c2fc9' User entered 'None (0)'	System	10 Sep 2020 04:32:23
	System	10 Sep 2020 04:32:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:27:18', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'aac68ae4-82e3-4ec7-aef8-1a92430c2fc9' User entered 'None (0)'	System	10 Sep 2020 04:32:23
	System	10 Sep 2020 04:32:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:27:23', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'aac68ae4-82e3-4ec7-aef8-1a92430c2fc9' User entered 'No (N)'	System	10 Sep 2020 04:32:23
	System	10 Sep 2020 04:32:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-09T23:32:19', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'aac68ae4-82e3-4ec7-aef8-1a92430c2fc9' User entered '09 Sep 2020 23:32'	System	10 Sep 2020 04:32:23
	System	10 Sep 2020 04:32:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 3'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:50:57', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'd372f66c-3b6d-4c21-bd27-6e76d489f2f0' User entered 'None (0)'	System	11 Sep 2020 14:51:36
	System	11 Sep 2020 14:51:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:51:05', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'd372f66c-3b6d-4c21-bd27-6e76d489f2f0' User entered 'None (0)'	System	11 Sep 2020 14:51:36
	System	11 Sep 2020 14:51:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:51:09', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'd372f66c-3b6d-4c21-bd27-6e76d489f2f0' User entered 'None (0)'	System	11 Sep 2020 14:51:36
	System	11 Sep 2020 14:51:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:51:11', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'd372f66c-3b6d-4c21-bd27-6e76d489f2f0' User entered 'None (0)'	System	11 Sep 2020 14:51:36
	System	11 Sep 2020 14:51:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:51:13', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'd372f66c-3b6d-4c21-bd27-6e76d489f2f0' User entered 'None (0)'	System	11 Sep 2020 14:51:36
	System	11 Sep 2020 14:51:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:51:16', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'd372f66c-3b6d-4c21-bd27-6e76d489f2f0' User entered 'None (0)'	System	11 Sep 2020 14:51:36
	System	11 Sep 2020 14:51:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:51:24', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'd372f66c-3b6d-4c21-bd27-6e76d489f2f0' User entered 'No (N)'	System	11 Sep 2020 14:51:36
	System	11 Sep 2020 14:51:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T09:51:35', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'd372f66c-3b6d-4c21-bd27-6e76d489f2f0' User entered '11 Sep 2020 09:51'	System	11 Sep 2020 14:51:36
	System	11 Sep 2020 14:51:36

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 4'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:39:01', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '38a26967-4c79-4e76-9afc-3cf4bae553bf' User entered 'None (0)'	System	12 Sep 2020 04:39:39
	System	12 Sep 2020 04:39:39

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:39:04', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '38a26967-4c79-4e76-9afc-3cf4bae553bf' User entered 'None (0)'	System	12 Sep 2020 04:39:39
	System	12 Sep 2020 04:39:39

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:39:07', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '38a26967-4c79-4e76-9afc-3cf4bae553bf' User entered 'None (0)'	System	12 Sep 2020 04:39:39
	System	12 Sep 2020 04:39:39

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:39:10', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '38a26967-4c79-4e76-9afc-3cf4bae553bf' User entered 'None (0)'	System	12 Sep 2020 04:39:39
	System	12 Sep 2020 04:39:39

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:39:12', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '38a26967-4c79-4e76-9afc-3cf4bae553bf' User entered 'None (0)'	System	12 Sep 2020 04:39:39
	System	12 Sep 2020 04:39:39

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:39:15', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '38a26967-4c79-4e76-9afc-3cf4bae553bf' User entered 'None (0)'	System	12 Sep 2020 04:39:39
	System	12 Sep 2020 04:39:39

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:39:21', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '38a26967-4c79-4e76-9afc-3cf4bae553bf' User entered 'No (N)'	System	12 Sep 2020 04:39:39
	System	12 Sep 2020 04:39:39

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-11T23:39:37', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '38a26967-4c79-4e76-9afc-3cf4bae553bf' User entered '11 Sep 2020 23:39'	System	12 Sep 2020 04:39:39
	System	12 Sep 2020 04:39:39

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 5'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:53:56', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60598bdf-508e-421c-8c2d-d001f4c5713d' User entered 'None (0)'	System	13 Sep 2020 04:54:23
	System	13 Sep 2020 04:54:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:53:59', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60598bdf-508e-421c-8c2d-d001f4c5713d' User entered 'None (0)'	System	13 Sep 2020 04:54:23
	System	13 Sep 2020 04:54:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:54:03', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60598bdf-508e-421c-8c2d-d001f4c5713d' User entered 'None (0)'	System	13 Sep 2020 04:54:23
	System	13 Sep 2020 04:54:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:54:06', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60598bdf-508e-421c-8c2d-d001f4c5713d' User entered 'None (0)'	System	13 Sep 2020 04:54:23
	System	13 Sep 2020 04:54:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:54:10', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60598bdf-508e-421c-8c2d-d001f4c5713d' User entered 'None (0)'	System	13 Sep 2020 04:54:23
	System	13 Sep 2020 04:54:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:54:13', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60598bdf-508e-421c-8c2d-d001f4c5713d' User entered 'None (0)'	System	13 Sep 2020 04:54:23
	System	13 Sep 2020 04:54:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:54:16', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60598bdf-508e-421c-8c2d-d001f4c5713d' User entered 'No (N)'	System	13 Sep 2020 04:54:23
	System	13 Sep 2020 04:54:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-12T23:54:19', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '60598bdf-508e-421c-8c2d-d001f4c5713d' User entered '12 Sep 2020 23:54'	System	13 Sep 2020 04:54:23
	System	13 Sep 2020 04:54:23

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 6'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:41', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b223772-0944-4c99-95f6-34d6c5f9960e' User entered 'None (0)'	System	14 Sep 2020 03:42:10
	System	14 Sep 2020 03:42:10

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:43', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b223772-0944-4c99-95f6-34d6c5f9960e' User entered 'None (0)'	System	14 Sep 2020 03:42:10
	System	14 Sep 2020 03:42:10

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:46', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b223772-0944-4c99-95f6-34d6c5f9960e' User entered 'None (0)'	System	14 Sep 2020 03:42:10
	System	14 Sep 2020 03:42:10

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:49', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b223772-0944-4c99-95f6-34d6c5f9960e' User entered 'None (0)'	System	14 Sep 2020 03:42:10
	System	14 Sep 2020 03:42:10

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:52', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b223772-0944-4c99-95f6-34d6c5f9960e' User entered 'None (0)'	System	14 Sep 2020 03:42:10
	System	14 Sep 2020 03:42:10

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:54', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b223772-0944-4c99-95f6-34d6c5f9960e' User entered 'None (0)'	System	14 Sep 2020 03:42:10
	System	14 Sep 2020 03:42:10

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:41:57', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b223772-0944-4c99-95f6-34d6c5f9960e' User entered 'No (N)'	System	14 Sep 2020 03:42:10
	System	14 Sep 2020 03:42:10

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-13T22:42:09', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '4b223772-0944-4c99-95f6-34d6c5f9960e' User entered '13 Sep 2020 22:42'	System	14 Sep 2020 03:42:10
	System	14 Sep 2020 03:42:10

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	08 Sep 2020 21:15:58
User entered 'Day 7'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:30', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '97ba2e00-fe08-4dc8-a70d-c070694123c1' User entered 'None (0)'	System	15 Sep 2020 05:12:52
	System	15 Sep 2020 05:12:52

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:32', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '97ba2e00-fe08-4dc8-a70d-c070694123c1' User entered 'None (0)'	System	15 Sep 2020 05:12:52
	System	15 Sep 2020 05:12:52

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:35', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '97ba2e00-fe08-4dc8-a70d-c070694123c1' User entered 'None (0)'	System	15 Sep 2020 05:12:52
	System	15 Sep 2020 05:12:52

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:38', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '97ba2e00-fe08-4dc8-a70d-c070694123c1' User entered 'None (0)'	System	15 Sep 2020 05:12:52
	System	15 Sep 2020 05:12:52

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:40', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '97ba2e00-fe08-4dc8-a70d-c070694123c1' User entered 'None (0)'	System	15 Sep 2020 05:12:52
	System	15 Sep 2020 05:12:52

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:42', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '97ba2e00-fe08-4dc8-a70d-c070694123c1' User entered 'None (0)'	System	15 Sep 2020 05:12:52
	System	15 Sep 2020 05:12:52

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

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)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:46', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '97ba2e00-fe08-4dc8-a70d-c070694123c1' User entered 'No (N)'	System	15 Sep 2020 05:12:52
	System	15 Sep 2020 05:12:52

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-09-15T00:12:50', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '97ba2e00-fe08-4dc8-a70d-c070694123c1' User entered '15 Sep 2020 00:12'	System	15 Sep 2020 05:12:52
	System	15 Sep 2020 05:12:52

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 21:15:58

US3032110

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:46:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 21:15:58

US3032110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:54:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4)	
	Samantha Wieseler (b) (4)	15 Sep 2020 22:20:18
	(b) (4)	

US3032110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:54:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '15 Sep 2020'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	15 Sep 2020 22:20:18

US3032110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:54:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wieseler (b) (4) (b) (4)	15 Sep 2020 22:20:18

US3032110

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:54:47
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) Samantha Wieseler (b) (4) (b) (4)	15 Sep 2020 22:20:18

US3032110

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:54:51
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4)	
	Samantha Wieseler (b) (4)	15 Sep 2020 22:20:21
	(b) (4)	

US3032110

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'I'	System	15 Sep 2020 22:20:21

US3032110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:55:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 21:13:47

US3032110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:55:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:13:47

US3032110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:55:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:13:47

US3032110

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:55:35
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:13:47

US3032110

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:55:38
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 21:13:51

US3032110

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'I'	System	22 Sep 2020 21:13:51

US3032110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:55:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 20:18:06

US3032110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:55:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered '29 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 20:18:06

US3032110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:55:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 20:18:06

US3032110

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:55:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 20:18:06

US3032110

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:55:53
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
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	29 Sep 2020 20:18:20
User entered 'Yes (Y)' reason for change: Data Entry Error	System	29 Sep 2020 20:18:20
User opened query 'Data is required. Please complete.' (Site from System).	Kelsey Kelley (b) (4)	29 Sep 2020 20:18:20
User entered empty.	(b) (4)	
	System	29 Sep 2020 20:18:09
	Kelsey Kelley (b) (4)	29 Sep 2020 20:18:09
	(b) (4)	

US3032110

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '1'	System	29 Sep 2020 20:18:20
User entered empty.	System	29 Sep 2020 20:18:09

US3032110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:59

US3032110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 01:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '13 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:59

US3032110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[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 00:01:31
DataPoint Verified.		26 Feb 2021 01:56:18
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:59

US3032110

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'VISIT3'	System	14 Oct 2020 16:15:59

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:03:09
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:03:12
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '13 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:03:05
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '15:30'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '13 Oct 2020 15:30'	System	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:03:07
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '37.3' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:03:02
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:03:01
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:02:57
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '94'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'bpm'	System	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:02:56
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'breaths/min'	System	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User closed query 'Per the source the systolic blood pressure is recorded as 146 please update or clarify ' (Site from CRA).		13 Apr 2021 14:10:33
DataPoint Verified.		13 Apr 2021 14:10:18
Query 'Per the source the systolic blood pressure is recorded as 146 please update or clarify ' answered with 'vitals had been retaken' (Site from CRA).		15 Mar 2021 16:26:23
User opened query 'Per the source the systolic blood pressure is recorded as 146 please update or clarify ' (Site from CRA).	(b) (4)	
Query 'Per the source systolic blood pressure is recorded as 146' canceled (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 02:02:50
User opened query 'Per the source systolic blood pressure is recorded as 146' (Site from CRA).		26 Feb 2021 01:59:04
User signature succeeded.		26 Feb 2021 01:58:55
User entered '122'		14 Oct 2020 19:30:45
	Keith Vrbicky (b) (4)	
	(b) (4)	
	Kelsey Kelley (b) (4)	14 Oct 2020 16:16:28
	(b) (4)	

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'mmHg'	System	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User closed query 'Per the source the diastolic blood pressure is recorded as 106 please update or clarify ' (Site from CRA).		13 Apr 2021 14:11:01
DataPoint Verified.		13 Apr 2021 14:10:50
Query 'Per the source the diastolic blood pressure is recorded as 106 please update or clarify ' answered with 'vitals had been retaken' (Site from CRA).	Samantha Wieseler (b) (4)	15 Mar 2021 16:26:34
User opened query 'Per the source the diastolic blood pressure is recorded as 106 please update or clarify ' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 02:01:48
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '66'	Kelsey Kelley (b) (4)	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'mmHg'	System	14 Oct 2020 16:16:28

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31

US3032110

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31

US3032110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:03:32
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:16:45

US3032110

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:03:32
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '13 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:16:45

US3032110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:03:44
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:17:02

US3032110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:03:44
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '13 Oct 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:17:02

US3032110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:03:44
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '15:59'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:17:02

US3032110

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '13 Oct 2020 15:59'	System	14 Oct 2020 16:17:02

US3032110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:03:47
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:17:05

US3032110

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered '1'	System	14 Oct 2020 16:17:05

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 64'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-10-06T17:18:16', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '169bb934-1134-4242-91e3-5cead6eccdf5'	System	06 Oct 2020 22:19:01
User entered 'No (N)'	System	06 Oct 2020 22:19:01

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-10-06T17:18:21', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '169bb934-1134-4242-91e3-5cead6eccdf5'	System	06 Oct 2020 22:19:01
User entered 'No (N)'	System	06 Oct 2020 22:19:01

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-10-06T17:18:37', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '169bb934-1134-4242-91e3-5cead6eccdf5' User entered '06 Oct 2020 17:18:37'	System	06 Oct 2020 22:19:01
	System	06 Oct 2020 22:19:01

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered '05 Oct 2020 00:01'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered '09 Oct 2020 23:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 71'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-10-13T08:54:18', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '009df812-d342-4b4e-b591-91064b64246d' User entered 'No (N)'	System	13 Oct 2020 14:33:19
	System	13 Oct 2020 14:33:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-10-13T08:54:26', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '009df812-d342-4b4e-b591-91064b64246d'	System	13 Oct 2020 14:33:19
User entered 'No (N)'	System	13 Oct 2020 14:33:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-10-13T08:54:31', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '009df812-d342-4b4e-b591-91064b64246d' User entered '13 Oct 2020 08:54:31'	System	13 Oct 2020 14:33:19
	System	13 Oct 2020 14:33:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered '12 Oct 2020 00:01'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered '16 Oct 2020 23:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 78'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-10-19T22:03:57', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '0f32b2a5-7fc0-4d55-8783-6ea179cc607c' User entered 'No (N)'	System	20 Oct 2020 03:04:14
	System	20 Oct 2020 03:04:14

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-10-19T22:04:03', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '0f32b2a5-7fc0-4d55-8783-6ea179cc607c'	System	20 Oct 2020 03:04:14
User entered 'No (N)'	System	20 Oct 2020 03:04:14

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-10-19T22:04:11', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '0f32b2a5-7fc0-4d55-8783-6ea179cc607c' User entered '19 Oct 2020 22:04:11'	System	20 Oct 2020 03:04:14
	System	20 Oct 2020 03:04:14

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered '19 Oct 2020 00:01'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered '23 Oct 2020 23:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 92'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-11-03T13:09:29', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'dd68db5a-4c79-4875-8bb6-c288e87448fd' User entered 'No (N)'	System	03 Nov 2020 19:09:56
	System	03 Nov 2020 19:09:56

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-11-03T13:09:37', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'dd68db5a-4c79-4875-8bb6-c288e87448fd' User entered 'No (N)'	System	03 Nov 2020 19:09:56
	System	03 Nov 2020 19:09:56

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-11-03T13:09:53', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'dd68db5a-4c79-4875-8bb6-c288e87448fd' User entered '03 Nov 2020 13:09:53'	System	03 Nov 2020 19:09:56
	System	03 Nov 2020 19:09:56

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered '02 Nov 2020 00:01'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered '06 Nov 2020 23:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 99'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-11-10T12:05:36', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1fbe7eaa-5e13-4c63-beb5-fa0d9303e6ec'	System	10 Nov 2020 17:06:06
User entered 'No (N)'	System	10 Nov 2020 17:06:06

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-11-10T12:05:46', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1fbe7eaa-5e13-4c63-beb5-fa0d9303e6ec'	System	10 Nov 2020 17:06:06
User entered 'No (N)'	System	10 Nov 2020 17:06:06

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-11-10T12:06:03', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1fbe7eaa-5e13-4c63-beb5-fa0d9303e6ec' User entered '10 Nov 2020 12:06:03'	System	10 Nov 2020 17:06:06
	System	10 Nov 2020 17:06:06

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered '09 Nov 2020 00:01'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:39:26
Data entry locked.	System	06 Aug 2020 01:05:51
User entered '13 Nov 2020 23:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19
Data entry locked.	System	06 Aug 2020 01:05:51
User entered 'Day 106'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19
Data entry locked.	System	06 Aug 2020 01:05:51
User entered '16 Nov 2020 00:01'	System	06 Aug 2020 01:05:51

US3032110

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:03:19
Data entry locked.	System	06 Aug 2020 01:05:51
User entered '20 Nov 2020 23:59'	System	06 Aug 2020 01:05:51

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-11-29T18:36:11', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '88a09da9-8b96-4789-828d-e361b0b2f321' User entered 'No (N)'	System	30 Nov 2020 00:36:44
	System	30 Nov 2020 00:36:44

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-11-29T18:36:19', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '88a09da9-8b96-4789-828d-e361b0b2f321' User entered 'Yes (Y)'	System	30 Nov 2020 00:36:44
	System	30 Nov 2020 00:36:44

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-11-29T18:36:25', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '88a09da9-8b96-4789-828d-e361b0b2f321'	System	30 Nov 2020 00:36:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Nov 2020 00:36:44

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-11-29T18:36:35', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '88a09da9-8b96-4789-828d-e361b0b2f321' User entered '29 Nov 2020 18:36:35'	System	30 Nov 2020 00:36:44

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-07T12:49:06', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3630dd42-8d20-4a05-963c-b4a41b3ce798'	System	07 Dec 2020 18:49:21
User entered 'No (N)'	System	07 Dec 2020 18:49:21

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-07T12:49:14', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3630dd42-8d20-4a05-963c-b4a41b3ce798'	System	07 Dec 2020 18:49:21
User entered 'No (N)'	System	07 Dec 2020 18:49:21

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-07T12:49:18', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '3630dd42-8d20-4a05-963c-b4a41b3ce798' User entered '07 Dec 2020 12:49:18'	System	07 Dec 2020 18:49:21
	System	07 Dec 2020 18:49:21

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-11T00:01:33', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'bdbb9dbb-f9d7-472c-b3f0-e7a4c3f50c85'	System	11 Dec 2020 06:01:57
User entered 'No (N)'	System	11 Dec 2020 06:01:57

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-11T00:01:40', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'bdbb9dbb-f9d7-472c-b3f0-e7a4c3f50c85'	System	11 Dec 2020 06:01:57
User entered 'No (N)'	System	11 Dec 2020 06:01:57

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-11T00:01:51', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'bdbb9dbb-f9d7-472c-b3f0-e7a4c3f50c85' User entered '11 Dec 2020 00:01:51'	System	11 Dec 2020 06:01:57
	System	11 Dec 2020 06:01:57

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-18T09:12:54', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'eca5e0b9-2b52-4534-a41c-abc96267ccf3'	System	18 Dec 2020 15:13:09
User entered 'No (N)'	System	18 Dec 2020 15:13:09

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-18T09:13:02', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'eca5e0b9-2b52-4534-a41c-abc96267ccf3'	System	18 Dec 2020 15:13:09
User entered 'No (N)'	System	18 Dec 2020 15:13:09

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-18T09:13:07', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'eca5e0b9-2b52-4534-a41c-abc96267ccf3' User entered '18 Dec 2020 09:13:07'	System	18 Dec 2020 15:13:09
	System	18 Dec 2020 15:13:09

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-28T08:50:02', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1fb68f6a-05c3-40b8-9007-0e83c0e44daa' User entered 'No (N)'	System	28 Dec 2020 14:52:06
	System	28 Dec 2020 14:52:06

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-28T08:50:11', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1fb68f6a-05c3-40b8-9007-0e83c0e44daa'	System	28 Dec 2020 14:52:06
User entered 'Yes (Y)'	System	28 Dec 2020 14:52:06

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Please 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-28T08:51:38', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1fb68f6a-05c3-40b8-9007-0e83c0e44daa'	System	28 Dec 2020 14:52:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 14:52:06

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2020-12-28T08:51:55', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '1fb68f6a-05c3-40b8-9007-0e83c0e44daa' User entered '28 Dec 2020 08:51:55'	System	28 Dec 2020 14:52:06
	System	28 Dec 2020 14:52:06

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-03T12:07:17', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '6b490f9b-5c73-4c74-96fe-8bed2abebb39'	System	03 Jan 2021 18:07:38
User entered 'No (N)'	System	03 Jan 2021 18:07:38

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-03T12:07:23', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '6b490f9b-5c73-4c74-96fe-8bed2abebb39'	System	03 Jan 2021 18:07:38
User entered 'No (N)'	System	03 Jan 2021 18:07:38

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-03T12:07:35', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '6b490f9b-5c73-4c74-96fe-8bed2abebb39' User entered '03 Jan 2021 12:07:35'	System	03 Jan 2021 18:07:38
	System	03 Jan 2021 18:07:38

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-08T02:01:20', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '7f17c01d-cdf4-444b-bb06-f0f8243058a5'	System	08 Jan 2021 08:01:36
User entered 'No (N)'	System	08 Jan 2021 08:01:36

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-08T02:01:24', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '7f17c01d-cdf4-444b-bb06-f0f8243058a5'	System	08 Jan 2021 08:01:36
User entered 'No (N)'	System	08 Jan 2021 08:01:36

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-08T02:01:27', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '7f17c01d-cdf4-444b-bb06-f0f8243058a5' User entered '08 Jan 2021 02:01:27'	System	08 Jan 2021 08:01:36
	System	08 Jan 2021 08:01:36

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-15T09:06:36', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '5d58951e-c5e4-4de0-a302-0cbfe8b0993c' User entered 'No (N)'	System	15 Jan 2021 15:06:55
	System	15 Jan 2021 15:06:55

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-15T09:06:39', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '5d58951e-c5e4-4de0-a302-0cbfe8b0993c' User entered 'No (N)'	System	15 Jan 2021 15:06:55

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-15T09:06:52', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '5d58951e-c5e4-4de0-a302-0cbfe8b0993c' User entered '15 Jan 2021 09:06:52'	System	15 Jan 2021 15:06:55
	System	15 Jan 2021 15:06:55

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-22T08:22:52', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '8e0aaf7b-debc-41ae-b11b-c435102f2634'	System	22 Jan 2021 13:23:06
User entered 'No (N)'	System	22 Jan 2021 13:23:06

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-22T08:22:58', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '8e0aaf7b-debc-41ae-b11b-c435102f2634'	System	22 Jan 2021 13:23:06
User entered 'No (N)'	System	22 Jan 2021 13:23:06

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-22T08:23:03', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '8e0aaf7b-debc-41ae-b11b-c435102f2634' User entered '22 Jan 2021 08:23:03'	System	22 Jan 2021 13:23:06
	System	22 Jan 2021 13:23:06

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-30T07:00:26', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '7c95a57e-8443-4454-8db0-72e84448e16b' User entered 'No (N)'	System	30 Jan 2021 13:00:38
	System	30 Jan 2021 13:00:38

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-30T07:00:31', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '7c95a57e-8443-4454-8db0-72e84448e16b'	System	30 Jan 2021 13:00:38
User entered 'No (N)'	System	30 Jan 2021 13:00:38

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-01-30T07:00:36', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '7c95a57e-8443-4454-8db0-72e84448e16b'	System	30 Jan 2021 13:00:38
User entered '30 Jan 2021 07:00:36'	System	30 Jan 2021 13:00:38

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-02-05T00:02:04', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '49cd9709-a984-4a2f-9c5b-6a86f38a655f'	System	05 Feb 2021 06:02:17
User entered 'No (N)'	System	05 Feb 2021 06:02:17

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-02-05T00:02:09', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '49cd9709-a984-4a2f-9c5b-6a86f38a655f'	System	05 Feb 2021 06:02:17
User entered 'No (N)'	System	05 Feb 2021 06:02:17

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-02-05T00:02:14', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '49cd9709-a984-4a2f-9c5b-6a86f38a655f' User entered '05 Feb 2021 00:02:14'	System	05 Feb 2021 06:02:17
	System	05 Feb 2021 06:02:17

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-02-12T00:01:15', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'acdce1d-7b1b-4db7-9542-70dc1b1fc134'	System	12 Feb 2021 06:01:44
User entered 'No (N)'	System	12 Feb 2021 06:01:44

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-02-12T00:01:20', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'acdce1d-7b1b-4db7-9542-70dc1b1fc134'	System	12 Feb 2021 06:01:44
User entered 'No (N)'	System	12 Feb 2021 06:01:44

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-02-12T00:01:27', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'acdce1d-7b1b-4db7-9542-70dc1b1fc134' User entered '12 Feb 2021 00:01:27'	System	12 Feb 2021 06:01:44
	System	12 Feb 2021 06:01:44

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-02-21T23:57:02', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '34005fa0-0258-423f-a156-28252cb310da' User entered 'Yes (Y)'	System	22 Feb 2021 05:57:46
	System	22 Feb 2021 05:57:46

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-02-21T23:57:15', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '34005fa0-0258-423f-a156-28252cb310da' User entered 'No (N)'	System	22 Feb 2021 05:57:46
	System	22 Feb 2021 05:57:46

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-02-21T23:57:26', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '34005fa0-0258-423f-a156-28252cb310da' User entered 'No (N)'	System	22 Feb 2021 05:57:46
	System	22 Feb 2021 05:57:46

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-02-21T23:57:33', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '34005fa0-0258-423f-a156-28252cb310da' User entered 'No (N)'	System	22 Feb 2021 05:57:46
	System	22 Feb 2021 05:57:46

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-02-21T23:57:42', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '34005fa0-0258-423f-a156-28252cb310da' User entered '21 Feb 2021 23:57:42'	System	22 Feb 2021 05:57:46

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-02T17:39:52-06:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '52a124da-6c8f-4c3f-bf7a-31619de6c674'	System	02 Mar 2021 23:40:06
User entered 'No (N)'	System	02 Mar 2021 23:40:06

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-02T17:39:56-06:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '52a124da-6c8f-4c3f-bf7a-31619de6c674'	System	02 Mar 2021 23:40:06
User entered 'No (N)'	System	02 Mar 2021 23:40:06

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-02T17:40:00-06:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '52a124da-6c8f-4c3f-bf7a-31619de6c674'	System	02 Mar 2021 23:40:06
User entered '02 Mar 2021 17:40:00'	System	02 Mar 2021 23:40:06

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-08T18:58:39-06:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'ff9dd7f8-235c-4242-9357-ef50cd4044f3'	System	09 Mar 2021 00:58:53
User entered 'No (N)'	System	09 Mar 2021 00:58:53

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-08T18:58:43-06:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'ff9dd7f8-235c-4242-9357-ef50cd4044f3'	System	09 Mar 2021 00:58:53
User entered 'No (N)'	System	09 Mar 2021 00:58:53

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-08T18:58:48-06:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'ff9dd7f8-235c-4242-9357-ef50cd4044f3'	System	09 Mar 2021 00:58:53
User entered '08 Mar 2021 18:58:48'	System	09 Mar 2021 00:58:53

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-21T19:30:26-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '28a62018-af55-44d1-b2e2-ee0128e28a46'	System	22 Mar 2021 00:30:41
User entered 'No (N)'	System	22 Mar 2021 00:30:41

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-21T19:30:30-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '28a62018-af55-44d1-b2e2-ee0128e28a46'	System	22 Mar 2021 00:30:41
User entered 'No (N)'	System	22 Mar 2021 00:30:41

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-21T19:30:37-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '28a62018-af55-44d1-b2e2-ee0128e28a46'	System	22 Mar 2021 00:30:41
User entered '21 Mar 2021 19:30:37'	System	22 Mar 2021 00:30:41

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-29T17:59:56-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f725d653-83ed-435d-a5bb-ec35b5ffcc76'	System	05 Apr 2021 23:59:12
User entered 'No (N)'	System	05 Apr 2021 23:59:12

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-29T17:59:59-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f725d653-83ed-435d-a5bb-ec35b5ffcc76'	System	05 Apr 2021 23:59:12
User entered 'No (N)'	System	05 Apr 2021 23:59:12

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-29T18:00:04-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f725d653-83ed-435d-a5bb-ec35b5ffcc76'	System	05 Apr 2021 23:59:12
User entered '29 Mar 2021 18:00:04'	System	05 Apr 2021 23:59:12

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-05T18:59:14-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '590e4e8f-e135-4065-a6ac-a0cf68d96fd4'	System	05 Apr 2021 23:59:24
User entered 'No (N)'	System	05 Apr 2021 23:59:24

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-05T18:59:18-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '590e4e8f-e135-4065-a6ac-a0cf68d96fd4'	System	05 Apr 2021 23:59:24
User entered 'No (N)'	System	05 Apr 2021 23:59:24

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-05T18:59:22-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '590e4e8f-e135-4065-a6ac-a0cf68d96fd4'	System	05 Apr 2021 23:59:24
User entered '05 Apr 2021 18:59:22'	System	05 Apr 2021 23:59:24

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-11T12:00:20-04:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '0eec5cac-3f9e-4c4f-b6fc-eef78cccf06'	System	11 Apr 2021 16:02:12
User entered 'No (N)'	System	11 Apr 2021 16:02:12

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-11T12:00:22-04:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '0eec5cac-3f9e-4c4f-b6fc-eef78cccf06'	System	11 Apr 2021 16:02:12
User entered 'No (N)'	System	11 Apr 2021 16:02:12

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-11T12:00:29-04:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '0eec5cac-3f9e-4c4f-b6fc-eef78cccf06'	System	11 Apr 2021 16:02:12
User entered '11 Apr 2021 12:00:29'	System	11 Apr 2021 16:02:12

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-19T18:27:45-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'c852bd99-cd4e-422f-805a-36018ed4d57b'	System	19 Apr 2021 23:27:55
User entered 'No (N)'	System	19 Apr 2021 23:27:55

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-19T18:27:50-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'c852bd99-cd4e-422f-805a-36018ed4d57b' User entered 'No (N)'	System	19 Apr 2021 23:27:55
	System	19 Apr 2021 23:27:55

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-19T18:27:53-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'c852bd99-cd4e-422f-805a-36018ed4d57b' User entered '19 Apr 2021 18:27:53'	System	19 Apr 2021 23:27:55
	System	19 Apr 2021 23:27:55

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-23T16:37:55-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '33dbc354-4632-4df4-82c4-692d8ed307ad' User entered 'No (N)'	System	23 Apr 2021 21:38:09
	System	23 Apr 2021 21:38:09

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-23T16:37:58-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '33dbc354-4632-4df4-82c4-692d8ed307ad' User entered 'No (N)'	System	23 Apr 2021 21:38:09
	System	23 Apr 2021 21:38:09

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-23T16:38:02-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: '33dbc354-4632-4df4-82c4-692d8ed307ad' User entered '23 Apr 2021 16:38:02'	System	23 Apr 2021 21:38:09
	System	23 Apr 2021 21:38:09

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-30T12:37:38-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'd359789b-7001-4186-804f-45cdad0b93a7'	System	30 Apr 2021 17:37:48
User entered 'No (N)'	System	30 Apr 2021 17:37:48

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

Have you been exposed to someone with 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 (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-30T12:37:43-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'd359789b-7001-4186-804f-45cdad0b93a7'	System	30 Apr 2021 17:37:48
User entered 'No (N)'	System	30 Apr 2021 17:37:48

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-04-30T12:37:46-05:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'd359789b-7001-4186-804f-45cdad0b93a7'	System	30 Apr 2021 17:37:48
User entered '30 Apr 2021 12:37:46'	System	30 Apr 2021 17:37:48

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 14:03:19

US3032110

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:46:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:03:19
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 14:03:19

US3032110

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:46:53

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 22:10:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-02T17:40:11-06:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f866ef7b-c732-4429-95c3-9c5e4c8cce55'	System	02 Mar 2021 23:40:21
User entered 'No (N)'	System	02 Mar 2021 23:40:21

US3032110

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:46:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:10:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90B01B83-995A-4D57-BFE2-0464FC061CDB)', Time: '2021-03-02T17:40:16-06:00', User OID: 'PatientReportedOutcome (US3032110)', ODM File OID: 'f866ef7b-c732-4429-95c3-9c5e4c8cce55'	System	02 Mar 2021 23:40:21
User entered '02 Mar 2021 17:40:16'	System	02 Mar 2021 23:40:21

US3032110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:05:08
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	20 Nov 2020 22:14:58

US3032110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:05:08
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '3 Nov 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	20 Nov 2020 22:14:58

US3032110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:05:08
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	20 Nov 2020 22:14:58

US3032110

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:05:08
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	20 Nov 2020 22:14:58

US3032110

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
DataPoint Verified.		26 Feb 2021 02:07:22
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Yes (Y)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	20 Nov 2020 22:15:03

US3032110

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:01:31
User entered 'I'	System	20 Nov 2020 22:15:03

US3032110

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
DataPoint Verified.		26 Feb 2021 02:10:41
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:09
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Dec 2020 18:26:45

US3032110

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
DataPoint Verified.		26 Feb 2021 02:10:41
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:09
User entered '7 Dec 2020'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Dec 2020 18:26:45

US3032110

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
DataPoint Verified.		26 Feb 2021 02:10:41
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Dec 2020 18:26:45

US3032110

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
DataPoint Verified.		26 Feb 2021 02:10:41
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:09
User entered empty.	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Dec 2020 18:26:45

US3032110

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
DataPoint Verified.		26 Feb 2021 02:10:45
User signature succeeded.	Keith Vrbicky (b) (4)	16 Dec 2020 20:07:09
User entered 'Yes (Y)'	(b) (4) Linden DeBoer (b) (4) (b) (4)	14 Dec 2020 18:26:50

US3032110

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User entered 'I'	System	14 Dec 2020 18:26:50

US3032110

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
DataPoint Verified.		26 Feb 2021 02:09:24
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:55:38

US3032110

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
DataPoint Verified.		26 Feb 2021 02:09:24
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:13
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:55:38

US3032110

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
DataPoint Verified.		26 Feb 2021 02:09:24
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:55:38

US3032110

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
DataPoint Verified.		26 Feb 2021 02:09:24
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:13
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:55:38

US3032110

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
DataPoint Verified.		26 Feb 2021 02:09:40
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:55:42

US3032110

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User entered 'I'	System	04 Feb 2021 14:55:42

US3032110

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:55:53

US3032110

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:13
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:55:53

US3032110

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:55:53

US3032110

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:13
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:55:53

US3032110

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 14:55:58

US3032110

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User entered 'I'	System	04 Feb 2021 14:55:58

US3032110

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	29 Mar 2021 20:14:38

US3032110

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered '17 Mar 2021'	Samantha Wieseler (b) (4)	29 Mar 2021 20:14:38

US3032110

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered 'Clinic (Clinic)'	Samantha Wieseler (b) (4)	29 Mar 2021 20:14:38

US3032110

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User entered 'VISIT4'	System	29 Mar 2021 20:14:38

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User closed query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 06:24:10
Query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' answered with 'if vitals are charted in visit 4 in EDC they will not match source due to protocol not wanting vitals for Visit 4, therefore vitals will not be input for visit 4. ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	20 Apr 2021 13:01:25
User opened query 'Per CDM, re-query: Thank you for your response, however, if a visit from Part A overlaps with a Visit from Part B and the visits occur on the same day, the data in assessments occurring in both visits must be identical. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:27:31
User closed query 'Per Sponsor review (RQ): Please note Visit 4 D209 and OL-D29 is done on the same date, Part A and Part B data needs to be consistent as both the visits are done on same date. Kindly reconcile and update. thanks ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:27:31
Query 'Per Sponsor review (RQ): Please note Visit 4 D209 and OL-D29 is done on the same date, Part A and Part B data needs to be consistent as both the visits are done on same date. Kindly reconcile and update. thanks ' answered with 'per protocol Visit 4 is not to have vitals. ' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	09 Apr 2021 17:19:55
User opened query 'Per Sponsor review (RQ): Please note Visit 4 D209 and OL-D29 is done on the same date, Part A and Part B data needs to be consistent as both the visits are done on same date. Kindly reconcile and update. thanks ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:12:50

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Were vital signs assessed?

Audit	User	Time (GMT)
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for Vital signs/Physical examination pages and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you. ' (Site from DM). Query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for Vital signs/Physical examination pages and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you.	(b) (4), (b) (6)	09 Apr 2021 11:12:50
' answered with 'Vitals are not done per protocol for visit 4' (Site from DM).		
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for Vital signs/Physical examination pages and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you.	(b) (4), (b) (6)	07 Apr 2021 18:56:34
' (Site from DM).		
User signature succeeded.	Keith Vrbicky (b) (4)	07 Apr 2021 07:04:41
	(b) (4)	
User entered 'No (N)'	Samantha Wieseler (b) (4)	07 Apr 2021 15:33:01
	(b) (4)	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered empty.	Samantha Wieseler (b) (4)	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User entered empty.	System	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered empty.	Samantha Wieseler (b) (4)	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered empty.	Samantha Wieseler (b) (4)	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered empty.	Samantha Wieseler (b) (4)	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered empty.	Samantha Wieseler (b) (4)	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User entered empty.	System	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User entered empty.	System	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User entered empty.	System	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered empty.	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16
User entered empty.	System	29 Mar 2021 20:14:44

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16

US3032110

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:13:16

US3032110

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered 'No (N)'	Samantha Wieseler (b) (4)	29 Mar 2021 20:14:57

US3032110

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered empty.	Samantha Wieseler (b) (4)	29 Mar 2021 20:14:57

US3032110

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	29 Mar 2021 20:15:10

US3032110

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered '17 Mar 2021'	Samantha Wieseler (b) (4)	29 Mar 2021 20:15:10

US3032110

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered '09:29'	Samantha Wieseler (b) (4)	29 Mar 2021 20:15:10

US3032110

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User entered '17 Mar 2021 09:29'	System	29 Mar 2021 20:15:10

US3032110

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered 'Yes (Y)'	(b) (4) Samantha Wieseler (b) (4)	29 Mar 2021 20:15:15

US3032110

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:32:20
User entered 'I'	System	29 Mar 2021 20:15:15

US3032110

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	05 Apr 2021 17:56:50

US3032110

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered '5 Apr 2021'	Chelsie Nutsch (b) (4)	05 Apr 2021 17:56:50

US3032110

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered 'Contact Made (CONTACT MADE)'	Chelsie Nutsch (b) (4)	05 Apr 2021 17:56:50

US3032110

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered empty.	(b) (4) Chelsie Nutsch (b) (4)	05 Apr 2021 17:56:50

US3032110

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:13
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered 'Yes (Y)'	Chelsie Nutsch (b) (4)	05 Apr 2021 17:56:53

US3032110

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:26:13
User entered 'I'	System	05 Apr 2021 17:56:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:46:53

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:13
DataPoint Verified.		26 Feb 2021 00:10:02
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '19 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:32:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:46:53

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:13
DataPoint Verified.		26 Feb 2021 00:10:02
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '11:20'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:32:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:46:53

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:13
User entered '19 Nov 2020 11:20'	System	19 Nov 2020 19:32:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:46:53

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:13
DataPoint Verified.		26 Feb 2021 00:10:02
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:32:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:46:53

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:13
DataPoint Verified.		26 Feb 2021 00:10:02
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:32:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Day 1 (Day 1)'	Russell Herstein (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '11 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'I'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered empty.	System	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 14:57:27
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:34:58
	(b) (4)	

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:34:58

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Day 2 (Day 2)'	Russell Herstein (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '12 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'I'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered empty.	System	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Day 3 (Day 3)'	Russell Herstein (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '13 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'I'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered empty.	System	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:35:49

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Day 4 (Day 4)'	Russell Herstein (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '14 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'I'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered empty.	System	19 Nov 2020 19:36:02

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	19 Nov 2020 19:36:02
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:02

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Day 5 (Day 5)'	Russell Herstein (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '15 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'I'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered empty.	System	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:12

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:22
User entered 'Day 6 (Day 6)'	Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '16 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'l'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered empty.	System	19 Nov 2020 19:36:22

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	19 Nov 2020 19:36:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	19 Nov 2020 19:36:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:22

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Day 7 (Day 7)'	Russell Herstein (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '17 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'I'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered empty.	System	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:36:47

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Day 8 (Day 8)'	Russell Herstein (b) (4)	19 Nov 2020 19:39:08

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '18 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered missing code ND - Not Done.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	19 Nov 2020 19:39:08

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered missing code ND - Not Done.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:39:08

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Day 9 (Day 9)'	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:40:27

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '19 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '98'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '36.7' C	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:40:27

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Day 10 (Day 10)'	(b) (4) Russell Herstein (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '20 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '92'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '97.8' F	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:07:47

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Day 11 (Day 11)'	(b) (4) Russell Herstein (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '21 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '96'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '97.9' F	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:08:38

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Day 12 (Day 12)'	(b) (4) Russell Herstein (b) (4)	23 Nov 2020 16:09:18

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:26
User closed query 'Per the source symptom day 12 was conducted on 22NOV20' (Site from CRA).	(b) (4)	24 Mar 2021 19:27:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:27:23
Query 'Per the source symptom day 12 was conducted on 22NOV20' answered with 'updated' (Site from CRA).	Samantha Wieseler (b) (4)	15 Mar 2021 16:26:01
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	15 Mar 2021 16:25:53
User entered '22 Nov 2020' reason for change: Data Entry Error	(b) (4)	15 Mar 2021 16:25:53
User opened query 'Per the source symptom day 12 was conducted on 22NOV20' (Site from CRA).	Samantha Wieseler (b) (4)	15 Mar 2021 16:25:53
DataPoint Verified.	(b) (4)	26 Feb 2021 00:34:59
User signature succeeded.	(b) (4), (b) (6)	26 Feb 2021 00:10:42
User entered '21 Nov 2020'	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
	(b) (4)	
	Russell Herstein (b) (4)	23 Nov 2020 16:09:18
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '95'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	23 Nov 2020 16:09:18

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '96.9' F	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:09:18

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Day 13 (Day 13)'	(b) (4) Russell Herstein (b) (4)	23 Nov 2020 16:10:11

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '23 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '95'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	23 Nov 2020 16:10:11

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '97.9' F	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Moderate (Moderate)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:10:11

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Day 14 (Day 14)'	(b) (4) Chelsie Nutsch (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '24 Nov 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '93'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '97.8' F	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	24 Nov 2020 22:44:51

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Day 15 (Day 15)'	Chelsie Nutsch (b) (4)	27 Nov 2020 23:19:13

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '25 Nov 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '96'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '97.5' F	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:19:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Day 16 (Day 16)'	Chelsie Nutsch (b) (4)	27 Nov 2020 23:20:44

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '26 Nov 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '93'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	27 Nov 2020 23:20:44

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '98.7' F	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:20:44

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Day 17 (Day 17)'	Chelsie Nutsch (b) (4)	27 Nov 2020 23:25:50

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '27 Nov 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '97'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	27 Nov 2020 23:25:50

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '98.9' F	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	27 Nov 2020 23:25:50

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Day 18 (Day 18)'	Chelsie Nutsch (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '28 Nov 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '96'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '98.7' F	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:39:37

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Day 19 (Day 19)'	Chelsie Nutsch (b) (4)	30 Nov 2020 00:40:55

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '29 Nov 2020'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '0'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '94'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '98.3' F	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Chelsie Nutsch (b) (4) (b) (4)	30 Nov 2020 00:40:55

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.		08 Dec 2020 19:46:58
User entered 'Day 20 (Day 20)'	Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '30 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '95'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '98.2' F	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Mild (Mild)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 15:21:56

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Day 21 (Day 21)'	Russell Herstein (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '01 Dec 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '94'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '98.8' F	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Russell Herstein (b) (4) (b) (4)	01 Dec 2020 21:18:29

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Day 22 (Day 22)'	Kelsey Kelley (b) (4)	02 Dec 2020 22:54:53

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '02 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '95'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
User entered '%'	System	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '97.9' F	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 14:46:53

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:22
DataPoint Verified.		26 Feb 2021 00:10:42
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'None (None)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:54:53

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:29
DataPoint Verified.		26 Feb 2021 00:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '19 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:04:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:29
DataPoint Verified.		26 Feb 2021 00:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:04:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:29
DataPoint Verified.		26 Feb 2021 00:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:20:35
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'ENTERED' (Site from System).	Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:04:17
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	23 Nov 2020 16:04:13
User entered 'Yes (Y)'	Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:04:13

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:29
DataPoint Verified.		26 Feb 2021 00:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '19 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:04:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:29
DataPoint Verified.		26 Feb 2021 00:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:04:13

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:29
DataPoint Verified.		26 Feb 2021 00:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:04:13

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[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)	28 Apr 2021 22:14:29
DataPoint Verified.		26 Feb 2021 00:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:04:13

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:29
DataPoint Verified.		26 Feb 2021 00:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:04:13

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Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:46:53

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:29
DataPoint Verified.		26 Feb 2021 00:40:11
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:04:13

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:29
User entered 'I'	System	23 Nov 2020 16:04:13

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:32:21
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:32:23
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	23 Nov 2020 16:06:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		09 Apr 2021 20:02:22
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	23 Nov 2020 16:06:40
	(b) (4)	

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:32:26
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:32:32
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:32:34
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		09 Apr 2021 20:02:29
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:32:36
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:32:46
User signature succeeded.	Keith Vrbicky (b) (4)	30 Jan 2021 16:47:27
User closed query 'Per ETRTR: Please confirm answer according to Symptoms log reported on 20Nov20, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:07:01
Query 'Per ETRTR: Please confirm answer according to Symptoms log reported on 20Nov20, thanks.' answered with 'DATA UPDATED' (Site from CRA).	Russell Herstein (b) (4) (b) (4)	01 Dec 2020 17:12:53
Signature has been broken.	Russell Herstein (b) (4) (b) (4)	01 Dec 2020 17:12:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	01 Dec 2020 17:12:44
User opened query 'Per ETRTR: Please confirm answer according to Symptoms log reported on 20Nov20, thanks.' (Site from CRA).	(b) (4), (b) (6)	27 Nov 2020 23:08:57
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:02:38
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:26
User closed query 'Per CDM: Per sponsor review, Did the subject have SpO2 < 93% is recorded as Yes. However, Start Date, End Date, and Oxygen Saturation are missing. Please review and update, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:34:56
User closed query 'Please verify as symptom log notes start date of severe O2 as 20Nov2020' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 21:26:08
Query 'Please verify as symptom log notes start date of severe O2 as 20Nov2020' answered with 'data updated' (Site from CRA).	Chelsie Nutsch (b) (4) (b) (4)	18 Mar 2021 19:14:33
Query 'Per CDM: Per sponsor review, Did the subject have SpO2 < 93% is recorded as Yes. However, Start Date, End Date, and Oxygen Saturation are missing. Please review and update, else clarify.' answered with 'data updated' (Site from DM).	Chelsie Nutsch (b) (4) (b) (4)	18 Mar 2021 19:14:25
Signature has been broken.	Chelsie Nutsch (b) (4) (b) (4)	18 Mar 2021 19:14:08
User entered '20 Nov 2020' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	18 Mar 2021 19:14:08
User opened query 'Please verify as symptom log notes start date of severe O2 as 20Nov2020' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 13:19:41
User opened query 'Per CDM: Per sponsor review, Did the subject have SpO2 < 93% is recorded as Yes. However, Start Date, End Date, and Oxygen Saturation are missing. Please review and update, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 15:38:15
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	24 Nov 2020 20:28:23
User entered empty.	Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:02:38
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:26
User closed query 'Please verify as symptom log notes last date of severe O2 as 26Nov2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 21:26:10
Query 'Please verify as symptom log notes last date of severe O2 as 26Nov2020' answered with 'data updated' (Site from CRA).	Chelsie Nutsch (b) (4) (b) (4)	18 Mar 2021 19:14:40
DataPoint Un-verified.	Chelsie Nutsch (b) (4) (b) (4)	18 Mar 2021 19:14:08
Signature has been broken.	Chelsie Nutsch (b) (4) (b) (4)	18 Mar 2021 19:14:08
User entered '26 Nov 2020' reason for change: Data Entry Error	Chelsie Nutsch (b) (4) (b) (4)	18 Mar 2021 19:14:08
User opened query 'Please verify as symptom log notes last date of severe O2 as 26Nov2020' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 13:20:13
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 01:34:14
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	24 Nov 2020 20:28:23
User entered empty.	Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.	(b) (4)	09 Apr 2021 20:02:38
User signature succeeded.	Keith Vrbicky (b) (4)	25 Mar 2021 14:17:26
User closed query 'Please verify as lowest O2 noted on symptom log was 92%' (Site from CRA).	(b) (4)	
Query 'Please verify as lowest O2 noted on symptom log was 92%' answered with 'data updated' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 21:26:12
DataPoint Un-verified.	Chelsie Nutsch (b) (4)	18 Mar 2021 19:14:46
Signature has been broken.	(b) (4)	
User entered '92' reason for change: Data Entry Error	Chelsie Nutsch (b) (4)	18 Mar 2021 19:14:08
User opened query 'Please verify as lowest O2 noted on symptom log was 92%' (Site from CRA).	(b) (4)	18 Mar 2021 19:14:08
DataPoint Verified.	Chelsie Nutsch (b) (4)	18 Mar 2021 13:20:32
User signature succeeded.	(b) (4), (b) (6)	26 Feb 2021 01:34:13
User entered empty.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
	(b) (4)	
	Russell Herstein (b) (4)	23 Nov 2020 16:06:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:07
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:19
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	23 Nov 2020 16:06:40
	(b) (4)	

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:21
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:23
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:26
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

US3032110

Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:28
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

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[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:30
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 01:34:33
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:38
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:39
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:45
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:47
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:49
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:50
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:54
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:56
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:34:59
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:04
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	23 Nov 2020 16:06:40
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:01
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:07
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:09
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:14
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:18
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:21
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:23
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:24
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:27
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:29
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:32
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:34
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:35:38
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:33:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:33:44
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:33:47
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:33:49
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:33:32
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:33:34
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 14:46:53

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:36
DataPoint Verified.		26 Feb 2021 01:33:37
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:06:40

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:46:53

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:43
DataPoint Verified.		26 Feb 2021 01:04:28
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:32:41

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
User accepted default value 'Day 3 (Day 3)'	Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.		26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.		26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '21 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
User accepted default value 'Day 5 (Day 5)'	Russell Herstein (b) (4)	30 Nov 2020 17:03:01
	(b) (4)	

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Yes (Y)'	Russell Herstein (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.		26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '23 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
User accepted default value 'Day 7 (Day 7)'	Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.		26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '25 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
User accepted default value 'Day 9 (Day 9)'	Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.		26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.		26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '27 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
User accepted default value 'Day 14 (Day 14)'	Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.		26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	02 Dec 2020 23:00:34
	(b) (4)	
User entered 'No (N)'	Russell Herstein (b) (4)	30 Nov 2020 17:03:01
	(b) (4)	

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.		26 Feb 2021 01:26:35
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		04 Jan 2021 18:44:00
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'data updated' (Site from DM).	Linden DeBoer (b) (4) (b) (4)	04 Jan 2021 14:38:59
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 04:55:52
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	08 Dec 2020 19:46:58
User entered '2 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 23:00:34
User entered empty.	Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
User accepted default value 'Day 21 (Day 21)'	Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.		26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
Signature has been broken.	(b) (4) Linden DeBoer (b) (4)	04 Jan 2021 14:39:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Linden DeBoer (b) (4)	04 Jan 2021 14:39:22
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	02 Dec 2020 23:00:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	02 Dec 2020 23:00:15
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 17:03:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Nov 2020 17:03:07
User entered 'No (N)' reason for change: Data Entry Error	Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:07
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 17:03:01
User entered empty.	Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.		26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
Signature has been broken.	(b) (4)	
	Linden DeBoer (b) (4)	04 Jan 2021 14:39:22
	(b) (4)	
User entered '09 Dec 2020' reason for change: Data Entry Error	Linden DeBoer (b) (4)	04 Jan 2021 14:39:22
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
	(b) (4)	
User entered empty; reason for change Data Entry Error	Kelsey Kelley (b) (4)	02 Dec 2020 23:00:24
	(b) (4)	
User entered '2 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	02 Dec 2020 23:00:15
	(b) (4)	
User entered empty.	Russell Herstein (b) (4)	30 Nov 2020 17:03:01
	(b) (4)	

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:46:53

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
User accepted default value 'Day 28 (Day 28)'	Russell Herstein (b) (4) (b) (4)	30 Nov 2020 17:03:01

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:46:53

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.		26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 17:06:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 17:06:49
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4)	30 Nov 2020 17:03:01
	(b) (4)	

US3032110

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:04
DataPoint Verified.		26 Feb 2021 01:26:35
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 17:06:49
User entered '16 Dec 2020' reason for change: Data Entry Error	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 17:06:49
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered empty.	(b) (4) Russell Herstein (b) (4)	30 Nov 2020 17:03:01
	(b) (4)	

US3032110

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:32
DataPoint Verified.		26 Feb 2021 00:13:28
User closed query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).		02 Dec 2020 17:24:53
Query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' answered with 'DATA IS UP TO DATE, SUBJECT WILL REACH DAY 14 ON 02 DEC 2020' (Site from CRA).	Russell Herstein (b) (4) (b) (4)	01 Dec 2020 16:43:22
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	27 Nov 2020 23:05:24
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:22
User entered 'Yes (Y)'	Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:24:38

US3032110

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:32
DataPoint Verified.		26 Feb 2021 00:13:28
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Russell Herstein (b) (4)	19 Nov 2020 19:27:28
	(b) (4)	
User entered '18 Nov 2020'	Russell Herstein (b) (4)	19 Nov 2020 19:24:38
	(b) (4)	

US3032110

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:32
DataPoint Verified.		26 Feb 2021 00:13:28
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Clinic (Clinic)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:24:38

US3032110

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:32
User entered 'SICKD1'	System	19 Nov 2020 19:24:38

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
DataPoint Verified.		26 Feb 2021 00:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
DataPoint Verified.		26 Feb 2021 00:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Nov 2020 19:27:28
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Nov 2020 19:27:28
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Nov 2020 19:27:04
User entered '19 Nov 2020'	Russell Herstein (b) (4)	19 Nov 2020 19:27:04
	(b) (4)	

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
DataPoint Verified.		26 Feb 2021 00:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '11:28'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
User entered '19 Nov 2020 11:28'	System	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
DataPoint Verified.		26 Feb 2021 00:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered missing code ND - Not Done.	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:27:04
DataPoint set to visible.	(b) (4) System	19 Nov 2020 19:24:38

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
DataPoint Verified.		26 Feb 2021 00:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered missing code ND - Not Done.	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:27:04
DataPoint set to visible.	(b) (4) System	19 Nov 2020 19:24:38

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
DataPoint Verified.		26 Feb 2021 00:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '36.7' C	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
DataPoint Verified.		26 Feb 2021 00:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Oral (Oral)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
DataPoint Verified.		26 Feb 2021 00:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
DataPoint Verified.		26 Feb 2021 00:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '72'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
User entered 'bpm'	System	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
DataPoint Verified.		26 Feb 2021 00:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '14'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
User entered 'breaths/min'	System	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
DataPoint Verified.		26 Feb 2021 00:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '134'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
User entered 'mmHg'	System	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
DataPoint Verified.		26 Feb 2021 00:13:52
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '78'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36
User entered 'mmHg'	System	19 Nov 2020 19:27:04

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36

US3032110

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:36

US3032110

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:39
DataPoint Verified.		26 Feb 2021 00:14:00
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:45

US3032110

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:39
DataPoint Verified.		26 Feb 2021 00:14:00
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '19 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:45

US3032110

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:46:53

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:43
DataPoint Verified.		26 Feb 2021 00:14:09
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:53

US3032110

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:43
DataPoint Verified.		26 Feb 2021 00:14:09
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '19 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:27:53

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:49
DataPoint Verified.		26 Feb 2021 01:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:55:07

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:49
DataPoint Verified.		26 Feb 2021 01:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered '16 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:55:07

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:49
DataPoint Verified.		26 Feb 2021 01:06:09
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:55:07

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:49
User entered 'SICKD28'	System	17 Dec 2020 14:55:07

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
DataPoint Verified.		26 Feb 2021 01:06:43
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
DataPoint Verified.		26 Feb 2021 01:06:43
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered '16 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
DataPoint Verified.		26 Feb 2021 01:06:43
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered '15:33'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
User entered '16 Dec 2020 15:33'	System	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
DataPoint Verified.		26 Feb 2021 01:06:43
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered '158.8' cm	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 14:56:19
DataPoint set to visible.	(b) (4) System	17 Dec 2020 14:55:07

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
DataPoint Verified.		26 Feb 2021 01:06:43
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered '71.0' kg	(b) (4) Kelsey Kelley (b) (4)	17 Dec 2020 14:56:19
DataPoint set to visible.	(b) (4) System	17 Dec 2020 14:55:07

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
DataPoint Verified.		26 Feb 2021 01:06:43
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered '36.8' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
DataPoint Verified.		26 Feb 2021 01:06:43
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
DataPoint Verified.		26 Feb 2021 01:06:43
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
DataPoint Verified.		26 Feb 2021 01:06:43
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered '68'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
User entered 'bpm'	System	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
DataPoint Verified.		26 Feb 2021 01:06:43
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
User entered 'breaths/min'	System	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
DataPoint Verified.		26 Feb 2021 01:06:43
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered '136'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
User entered 'mmHg'	System	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
DataPoint Verified.		26 Feb 2021 01:06:43
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered '71'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52
User entered 'mmHg'	System	17 Dec 2020 14:56:19

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:46:53

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:52

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:56
DataPoint Verified.		26 Feb 2021 01:07:00
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:25

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:48:56
DataPoint Verified.		26 Feb 2021 01:07:00
User signature succeeded.	Keith Vrbicky (b) (4)	23 Dec 2020 15:53:20
User entered '16 Dec 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:25

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:46:53

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:00
DataPoint Verified.		26 Feb 2021 01:08:05
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:31

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:49:00
DataPoint Verified.		26 Feb 2021 01:08:05
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 16 DEC 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).		02 Feb 2021 05:38:44
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 16 DEC 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' answered with 'Accession Number: 1F63098' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	19 Jan 2021 23:17:37
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per previous query response, Since the sample was shipped, please provide the Accession number and Tracking number with the shipping date for the 16 DEC 2020 SARS-CoV-2 serum sample reported under Convalescence Visit Day 28, to track the sample in PPD central lab as the sample is still missing in PPD central lab.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:39:53
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	07 Jan 2021 19:15:51

US3032110

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:46:53

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 DEC 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum 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)	24 Dec 2020 04:40:56
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 DEC 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum 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 'samples have been shipped' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	23 Dec 2020 19:20:00
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 16 DEC 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum 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)	22 Dec 2020 08:55:47
User entered '16 Dec 2020'	Kelsey Kelley (b) (4) (b) (4)	17 Dec 2020 14:56:31

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:13:11
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:26:42

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:13:11
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '18 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:26:42

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:13:11
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:26:42

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'UNBLND_DECIDE'	System	18 Feb 2021 23:26:42

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:15:56
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '18 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:27:00

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:38:22

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:15:56
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4)	
	System	18 Feb 2021 23:27:07
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System).	System	18 Feb 2021 23:27:07
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	18 Feb 2021 23:27:00
User entered 'Yes (Y)'	Kelsey Kelley (b) (4)	18 Feb 2021 23:27:00
	(b) (4)	

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:38:22

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:15:56
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '18 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	18 Feb 2021 23:27:07
User entered empty.	(b) (4)	
	Kelsey Kelley (b) (4)	18 Feb 2021 23:27:00
	(b) (4)	

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:15:56
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:27:00

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:15:56
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:27:00

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:15:56
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Placebo (Placebo)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:27:00

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:15:56
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:27:00

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '1'	System	18 Feb 2021 23:27:00

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:46:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'I'	System	18 Feb 2021 23:27:00

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered empty.	System	18 Feb 2021 23:29:25
DataPoint set to visible.	System	18 Feb 2021 23:27:00

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered empty.	System	18 Feb 2021 23:29:25
DataPoint set to visible.	System	18 Feb 2021 23:27:00

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '18 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '11:58'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '18 Feb 2021 11:58'	System	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '36.6' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '76'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'bpm'	System	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '16'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'breaths/min'	System	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '140'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'mmHg'	System	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '90'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'mmHg'	System	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered missing code ND - Not Done.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:29:25

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:46:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered empty.	System	18 Feb 2021 23:29:25
DataPoint set to visible.	System	18 Feb 2021 23:27:00

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '18 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '13:15'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '18 Feb 2021 13:15'	System	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '36.6' C	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '73'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'bpm'	System	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '14'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'breaths/min'	System	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '140'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'mmHg'	System	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:03
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '90'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'mmHg'	System	18 Feb 2021 23:30:38

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:27:17

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:15
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User closed query 'The Physical Examination Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	18 Feb 2021 23:27:26
User closed query 'The physical examination date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	18 Feb 2021 23:27:26
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Feb 2021 23:27:26
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	18 Feb 2021 23:27:26
User entered '18 Feb 2021' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:27:26
User opened query 'The Physical Examination Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	18 Feb 2021 23:27:17
User opened query 'The physical examination date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	18 Feb 2021 23:27:17
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Feb 2021 23:27:17
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	18 Feb 2021 23:27:17
User entered '18 Feb 2012'	Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:27:17

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:52
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:15

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:52
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:15

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

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 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:52
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:15

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'mRNA-1273'	System	18 Feb 2021 23:30:15
DataPoint set to visible.	System	18 Feb 2021 23:27:00

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:52
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '18 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:15

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:52
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '12:42'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:15

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '18 Feb 2021 12:42'	System	18 Feb 2021 23:30:15

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:52
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:30:15

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:16:52
User entered 'ONCE'	System	18 Feb 2021 23:30:15

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'INTRAMUSCULAR'	System	18 Feb 2021 23:30:15

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:17:05
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:28:12

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:17:05
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '18 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:28:12

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:17:05
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '11:40'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:28:12

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:46:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '18 Feb 2021 11:40'	System	18 Feb 2021 23:28:12

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:46:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:17:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:28:21

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:46:53

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:17:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '18 Feb 2021'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:28:21

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:46:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:17:09
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered '11:45'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:28:21

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:46:53

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '18 Feb 2021 11:45'	System	18 Feb 2021 23:28:21

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
DataPoint Verified.		26 Feb 2021 02:17:12
User signature succeeded.	Keith Vrbicky (b) (4)	22 Feb 2021 17:23:18
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	18 Feb 2021 23:28:23

US3032110

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'I'	System	18 Feb 2021 23:28:23

US3032110

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	10 Mar 2021 20:40:50

US3032110

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '25 Feb 2021'	Linden DeBoer (b) (4)	10 Mar 2021 20:40:50

US3032110

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Contact Made (CONTACT MADE)'	Linden DeBoer (b) (4)	10 Mar 2021 20:40:50

US3032110

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered empty.	Linden DeBoer (b) (4)	10 Mar 2021 20:40:50

US3032110

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Yes (Y)'	Linden DeBoer (b) (4)	10 Mar 2021 20:40:55

US3032110

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User entered 'I'	System	10 Mar 2021 20:40:55

US3032110

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User entered '1'	System	10 Mar 2021 20:40:55
DataPoint set to visible.	System	10 Mar 2021 20:40:55

US3032110

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 16:51:20

US3032110

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '17 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 16:51:20
	(b) (4)	

US3032110

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Clinic (Clinic)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 16:51:20

US3032110

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:46:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'OLD29'	System	17 Mar 2021 16:51:20

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User accepted default value 'Pre-Dose (PREDOSE)'	Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 17:01:52

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:01:52

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '17 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:01:52
	(b) (4)	

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '09:25'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:01:52

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '17 Mar 2021 09:25'	System	17 Mar 2021 17:01:52

(

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '36.5' C	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:01:52
	(b) (4)	

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:01:52
	(b) (4)	

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:01:52
	(b) (4)	

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '76'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:01:52

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'bpm'	System	17 Mar 2021 17:01:52

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	17 Mar 2021 17:02:06
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).		17 Mar 2021 17:02:06
User entered '16' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	17 Mar 2021 17:02:06
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	17 Mar 2021 17:01:52
User entered '6'	Kelsey Kelley (b) (4)	17 Mar 2021 17:01:52

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'breaths/min'	System	17 Mar 2021 17:01:52

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '137'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:01:52

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'mmHg'	System	17 Mar 2021 17:01:52

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '86'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:01:52

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'mmHg'	System	17 Mar 2021 17:01:52

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User accepted default value 'Post-Dose (POSTDOSE)'	Kelsey Kelley (b) (4) (b) (4)	17 Mar 2021 17:04:54

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:54

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '17 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:54
	(b) (4)	

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '11:20'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:54

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '17 Mar 2021 11:20'	System	17 Mar 2021 17:04:54

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '36.7' C	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:54
	(b) (4)	

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Oral (Oral)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:54
	(b) (4)	

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:54
	(b) (4)	

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '76'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:54

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'bpm'	System	17 Mar 2021 17:04:54

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '14'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:54

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'breaths/min'	System	17 Mar 2021 17:04:54

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '140'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:54

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'mmHg'	System	17 Mar 2021 17:04:54

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '88'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:54

US3032110

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:46:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'mmHg'	System	17 Mar 2021 17:04:54

US3032110

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:03:19

US3032110

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:46:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '17 Mar 2021'	Kelsey Kelley (b) (4)	17 Mar 2021 17:03:19

US3032110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:15

US3032110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:15
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

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 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:15
	(b) (4)	

US3032110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'mRNA-1273'	System	17 Mar 2021 17:04:15
DataPoint set to visible.	System	10 Mar 2021 20:40:55

US3032110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '17 Mar 2021'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:15
	(b) (4)	

US3032110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered '10:45'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:15

US3032110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered '17 Mar 2021 10:45'	System	17 Mar 2021 17:04:15

US3032110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Left Arm (LEFT ARM)'	Kelsey Kelley (b) (4)	17 Mar 2021 17:04:15

US3032110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'ONCE'	System	17 Mar 2021 17:04:15

US3032110

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:46:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'INTRAMUSCULAR'	System	17 Mar 2021 17:04:15

US3032110

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User signature succeeded.	Keith Vrbicky (b) (4)	18 Mar 2021 21:10:51
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	17 Mar 2021 17:04:19

US3032110

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:52:04
User entered 'I'	System	17 Mar 2021 17:04:19

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	29 Mar 2021 19:20:00

US3032110

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered '25 Mar 2021'	Samantha Wieseler (b) (4)	29 Mar 2021 19:20:00

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered 'Contact Made (CONTACT MADE)'	Samantha Wieseler (b) (4)	29 Mar 2021 19:20:00

US3032110

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:46:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered empty.	Samantha Wieseler (b) (4)	29 Mar 2021 19:20:00

US3032110

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User signature succeeded.	Keith Vrbicky (b) (4)	06 Apr 2021 15:33:01
User entered 'Yes (Y)'	Samantha Wieseler (b) (4)	29 Mar 2021 19:20:03

US3032110

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:46:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:12:23
User entered 'I'	System	29 Mar 2021 19:20:03

US3032110

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:46:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	May 2021 12:47:46
DataPoint Verified.		Apr 2021 20:06:20
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:16:36

US3032110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:19
User entered 'USA-US032-2020-mRNA-1273-P301000013'	System	20 Nov 2020 19:55:01
User entered 'New'	(b) (4), (b) (6)	20 Nov 2020 19:55:01

US3032110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
User closed query 'Per CDM: Please note that the confirmed COVID-19 diagnosis should be recorded as either COVID-19 or SYMPTOMATIC COVID-19. Kindly update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 05:46:51
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 22:56:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 22:56:48
Data point term sent to Coder	System	02 Dec 2020 22:56:15
Query 'Per CDM: Please note that the confirmed COVID-19 diagnosis should be recorded as either COVID-19 or SYMPTOMATIC COVID-19. Kindly update as appropriate. ' answered with 'data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:55:39
Coding entries removed.	Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:55:34
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:55:34
User entered 'COVID-19' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	02 Dec 2020 22:55:34
User opened query 'Per CDM: Please note that the confirmed COVID-19 diagnosis should be recorded as either COVID-19 or SYMPTOMATIC COVID-19. Kindly update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:45:05
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:20:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:20:09
Data point term sent to Coder	System	19 Nov 2020 19:19:23
User entered 'covid-19 infection'	Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:18:28

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
Signature has been broken.	Linden DeBoer (b) (4)	24 Nov 2020 21:04:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Linden DeBoer (b) (4)	24 Nov 2020 21:04:45
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'No (N)'	Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:18:28

US3032110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	14 Apr 2021 19:19:54
User closed query 'Per the source the start day was 11NOV please clarify or update' (Site from CRA). DataPoint Verified.	(b) (4) (u) (4), (b) (6)	13 Apr 2021 14:09:30 13 Apr 2021 14:09:18
Query 'Per the source the start day was 11NOV please clarify or update' answered with 'updated' (Site from CRA).	Samantha Wieseler (b) (4) (b) (4)	13 Apr 2021 13:35:50
Signature has been broken.	Samantha Wieseler (b) (4) (b) (4)	13 Apr 2021 13:35:32
User entered '11 Nov 2020' reason for change: Data Entry Error	Samantha Wieseler (b) (4) (b) (4)	13 Apr 2021 13:35:32
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:32
DataPoint Verified.		09 Apr 2021 20:08:26
User opened query 'Per the source the start day was 11NOV please clarify or update' (Site from CRA).		09 Apr 2021 20:08:12
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:22
User entered '18 Nov 2020'	Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	19 Nov 2020 19:18:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
Signature has been broken.	(b) (4)	
	Kelsey Kelley (b) (4)	02 Dec 2020 22:57:42
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	02 Dec 2020 22:57:42
	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
	(b) (4)	
User entered 'Yes (Y)'	Russell Herstein (b) (4)	19 Nov 2020 19:18:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:21
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
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	02 Dec 2020 22:58:03
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	02 Dec 2020 22:58:03
Signature has been broken.	System	02 Dec 2020 22:57:42
User entered '1 Dec 2020' reason for change: Data Entry Error	Kelsey Kelley (b) (4)	02 Dec 2020 22:57:42
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	02 Dec 2020 22:57:42
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'WILL UPDATE; SUBJECT IS STILL HAVING SYMPTOMS, THIS IS WHY MARKED AS ONGOING' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 20:09:18
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	
User signature succeeded.	Russell Herstein (b) (4)	24 Nov 2020 20:58:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 20:51:51
	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
	(b) (4)	
	Russell Herstein (b) (4)	19 Nov 2020 19:18:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
Signature has been broken.	Chelsie Nutsch (b) (4)	24 Nov 2020 23:36:01
User entered 'Grade 3/Severe (Grade 3/Severe)'	Chelsie Nutsch (b) (4)	24 Nov 2020 23:36:01
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Russell Herstein (b) (4)	19 Nov 2020 19:18:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '0'	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:18:28

US3032110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '0'	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '0'	Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	19 Nov 2020 19:18:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	19 Nov 2020 19:18:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4)	
	Russell Herstein (b) (4)	19 Nov 2020 19:18:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '0'	Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '0'	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '0'	Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Not Related (NOT RELATED)'	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Not Related (NOT RELATED)'	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Russell Herstein (b) (4)	19 Nov 2020 19:18:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Signature has been broken.	(b) (4)	
	Russell Herstein (b) (4)	23 Nov 2020 16:11:55
User signature succeeded.	(b) (4)	
	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '0'	(b) (4)	
	Russell Herstein (b) (4)	19 Nov 2020 19:18:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'I'	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:18:28

US3032110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '0'	Russell Herstein (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
Signature has been broken.	(b) (4) Kelsey Kelley (b) (4)	02 Dec 2020 22:58:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) Kelsey Kelley (b) (4)	02 Dec 2020 22:58:03
Data Entry Error	(b) (4)	
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 20:09:24
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'recovering/resolving' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 21:06:49
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:51:37
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:18:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4)	19 Nov 2020 19:18:28

US3032110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:08:26
User closed query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 23:57:00
Query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'this is up to date ' (Site from Safety).	Kelsey Kelley (b) (4) (b) (4)	29 Dec 2020 16:53:09
User opened query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 18:15:13
User closed query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 20:09:26
Query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment. ' answered with 'data was entered' (Site from Safety).	Linden DeBoer (b) (4) (b) (4)	24 Nov 2020 21:06:23
User opened query 'PV Query: Please complete the COVID-19 Assessments tab, including results of COVID-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:51:05
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:22
User entered empty.	Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:18:28

US3032110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 19:18:28

US3032110

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:46:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:04:45
User entered '0'	System	19 Nov 2020 19:18:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:46:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:46
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 01:05:07
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:07:14

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 14:10:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 14:10:17
Data point term sent to Coder	System	06 Aug 2020 14:08:58
User entered 'levothyroxine'	Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'medical history: hypothyroidism'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered '150'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	29 Sep 2020 20:16:41
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	29 Sep 2020 20:16:41
User entered 'mcg'	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:18:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 14:08:21
User entered 'un UNK 2019'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:08:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:32:48
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:08:21

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 14:08:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 14:08:21

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 14:08:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:14:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:14:18
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:22
Data point term sent to Coder	System	17 Nov 2020 23:46:42
Coding entries removed.	Linden DeBoer (b) (4) (b) (4)	17 Nov 2020 23:45:47
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	17 Nov 2020 23:45:47
User entered 'LIOthyROxINE' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	17 Nov 2020 23:45:47
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:50:13
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOthyRONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:06:18
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 Aug 2020 07:06:18
Data point term sent to Coder	System	06 Aug 2020 14:10:02
User entered 'liothyronine'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:09:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'medical history: hypothyroidism'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered '5'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	29 Sep 2020 20:17:17
User entered 'Other (OTHER)'	Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kelsey Kelley (b) (4)	29 Sep 2020 20:17:17
User entered 'mcg'	(b) (4)	
	Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:18:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 14:09:10
User entered 'un UNK 2019'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:09:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:30
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:09:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 14:09:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 14:09:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 14:09:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:30:26
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 22:30:26
Data point term sent to Coder Coding entries removed.	System Kelsey Kelley (b) (4)	14 Oct 2020 16:13:55 14 Oct 2020 16:13:24
User signature succeeded.	(b) (4) Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 05:16:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 05:16:02
Data point term sent to Coder Coding entries removed.	System Samantha Wieseler (b) (4)	15 Sep 2020 22:20:27 15 Sep 2020 22:19:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Aug 2020 17:54:13

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	07 Aug 2020 17:54:13
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	06 Aug 2020 14:11:03
User entered 'meloxicam'	Kelsey Kelley (b) (4)	06 Aug 2020 14:10:06
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:06
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User closed query 'Per DM CLR: Note there is no Medical History Condition LEGS MUSCLE SPASMS that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).		22 Oct 2020 09:48:23
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
Query 'Per DM CLR: Note there is no Medical History Condition LEGS MUSCLE SPASMS that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' answered with 'updated' (Site from DM).	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:13:39
Signature has been broken.	Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:13:24
User entered 'MEDICAL HISTORY: muscle spasms of lower back' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:13:24
User opened query 'Per DM CLR: Note there is no Medical History Condition LEGS MUSCLE SPASMS that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 10:30:01
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:50:13
User closed query 'Per DM CLR: Please update the indication to reflect the location of MUSCLE TENSION . Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 07:18:54
Query 'Per DM CLR: Please update the indication to reflect the location of MUSCLE TENSION . Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'updated' (Site from DM).	Samantha Wieseler (b) (4) (b) (4)	15 Sep 2020 22:19:50

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
User entered 'MEDICAL HISTORY: BACK and legs MUSCLE SPASMS' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	15 Sep 2020 22:19:42
User entered 'MEDICAL HISTORY: back MUSCLE SPASMS' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	15 Sep 2020 22:19:33
User opened query 'Per DM CLR: Please update the indication to reflect the location of MUSCLE TENSION . Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:26:51
User entered 'medical history: muscle spasms'	Kelsey Kelley (b) (4)	06 Aug 2020 14:10:06

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User closed query 'Per DM CLR: Please review recorded dose and please update to record the actual dose rather than to add/include the dose field the number of tablet taken. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 06:44:57
Query 'Per DM CLR: Please review recorded dose and please update to record the actual dose rather than to add/include the dose field the number of tablet taken. Please update as appropriate or provide clarification.' answered with ' data updated' (Site from DM).	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 20:16:17
User entered '15' reason for change: Data Entry Error	Kelsey Kelley (b) (4) (b) (4)	29 Sep 2020 20:16:11
User opened query 'Per DM CLR: Please review recorded dose and please update to record the actual dose rather than to add/include the dose field the number of tablet taken. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:25:25
User entered '15 (1/2 tablet)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:10:06

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:06
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:06
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).		02 Feb 2021 15:02:18
Query 'Per DM CLR: Please review the Frequency as Samantha Wieseler this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' answered with 'subject takes medication twice daily' (Site from DM).	(b) (4) (b) (4)	01 Feb 2021 20:04:57
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:20:45
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	20 Nov 2020 16:29:22
Signature has been broken.	Linden DeBoer (b) (4) (b) (4)	17 Nov 2020 23:46:03
User entered 'twice daily (BID)' reason for change: Data Entry Error	Linden DeBoer (b) (4) (b) (4)	17 Nov 2020 23:46:03
User signature succeeded.	Keith Vrbicky (b) (4) (b) (4)	01 Oct 2020 21:50:13
User entered 'once daily (QD)'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:10:06

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:06

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:06
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:06
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:18:43
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 14:10:06
User entered 'un UNK 2019'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:10:06

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:06

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:06

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:06
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:35
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:06

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Nov 2020 23:46:03
User entered '1'	System	06 Aug 2020 14:10:06

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 14:10:06

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 14:10:06

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 14:12:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 14:12:14
Data point term sent to Coder	System	06 Aug 2020 14:11:03
User entered 'atorvastatin'	Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'medical history: hypercholesterolemia'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered '20'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	Loren Hodges (b) (4)	12 Aug 2020 14:18:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 14:10:41
User entered 'un UNK 2019'	Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:42
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
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	18 Aug 2020 14:06:50
User entered 'No (N)' reason for change: Data Entry Error	System	18 Aug 2020 14:06:50
User opened query 'Data is required. Please complete.' (Site from System).	Kelsey Kelley (b) (4)	18 Aug 2020 14:06:50
User entered empty.	(b) (4)	
	System	06 Aug 2020 14:10:41
	Kelsey Kelley (b) (4)	06 Aug 2020 14:10:41
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 14:10:41

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 14:13:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 14:13:16
Data point term sent to Coder	System	06 Aug 2020 14:12:06
User entered 'omeprazole'	Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'medical history: acid reflux'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered '40'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'mg (mg)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'once daily (QD)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Oral (ORAL)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:19:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 14:11:10
User entered 'un UNK 2019'	Kelsey Kelley (b) (4) (b) (4)	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered '0'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered empty.	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:35:50
User signature succeeded.	Keith Vrbicky (b) (4)	01 Oct 2020 21:50:13
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 14:11:10

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Oct 2020 16:24:50
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 16:24:50
Data point term sent to Coder	System	14 Oct 2020 16:15:59
User entered 'seasonal influenza vaccine'	Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'Yes (Y)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'prevention of seasonal influenza'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '0.5'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'mL (mL)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'once (ONCE)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered empty.	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '24 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '0'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered '24 Sep 2020'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
DataPoint Verified.		24 Mar 2021 20:36:50
User signature succeeded.	Keith Vrbicky (b) (4)	14 Oct 2020 19:30:45
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4) (b) (4)	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
User entered empty.	System	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
User entered empty.	System	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:04:05
User entered empty.	System	14 Oct 2020 16:15:17

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Nov 2020 22:22:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 22:22:06
Data point term sent to Coder	System	19 Nov 2020 19:22:31
User entered 'dexamethasone'	Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'covid-19 infection'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '6'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'mg (mg)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'once daily (QD)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Oral (ORAL)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '18 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.	(b) (4)	06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:13
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.'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:03:03
(Site from DM).		
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.'	Samantha Wieseler (b) (4)	01 Feb 2021 20:05:40
' answered with 'updated' (Site from DM).	(b) (4)	
Signature has been broken.	Samantha Wieseler (b) (4)	01 Feb 2021 20:05:35
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wieseler (b) (4)	01 Feb 2021 20:05:35
	(b) (4)	
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.'	(b) (4), (b) (6)	29 Jan 2021 09:21:05
(Site from DM).		
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Russell Herstein (b) (4)	19 Nov 2020 19:22:15
	(b) (4)	
User entered 'No (N)'	Russell Herstein (b) (4)	19 Nov 2020 19:22:02
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
User signature succeeded.	Keith Vrbicky (b) (4)	09 Apr 2021 18:06:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:24:21
User closed query 'Per the source this medication end date was 24NOV21 please refer to the source and update' (Site from CRA).		06 Apr 2021 16:24:16
Query 'Per the source this medication end date was 24NOV21 please refer to the source and update' answered with 'updated' (Site from CRA).	Samantha Wieseler (b) (4)	26 Mar 2021 14:18:27
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	26 Mar 2021 14:18:09
User entered '24 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	26 Mar 2021 14:18:09
User opened query 'Per the source this medication end date was 24NOV21 please refer to the source and update' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 20:20:35
User signature succeeded.	Keith Vrbicky (b) (4)	05 Feb 2021 19:39:13
Signature has been broken.	(b) (4)	
	Samantha Wieseler (b) (4)	01 Feb 2021 20:05:35
User entered '01 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Samantha Wieseler (b) (4)	01 Feb 2021 20:05:35
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
	System	19 Nov 2020 19:22:15
User entered empty; reason for change Data Entry Error	Russell Herstein (b) (4)	19 Nov 2020 19:22:15
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	19 Nov 2020 19:22:02
User entered '24 Nov 2020'	Russell Herstein (b) (4)	19 Nov 2020 19:22:02
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
DataPoint Verified.		06 Apr 2021 16:24:21
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
User entered '1'	System	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
User entered '1'	System	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:19:50
User entered '804 (804)'	System	19 Nov 2020 19:22:02

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Nov 2020 19:24:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:24:02
Data point term sent to Coder	System	19 Nov 2020 19:23:35
User entered 'azithromycin'	Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'covid-19 infection'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '500'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'mg (mg)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'once (ONCE)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'Oral (ORAL)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '19 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered '19 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
DataPoint Verified.		24 Mar 2021 21:09:23
User signature succeeded.	Keith Vrbicky (b) (4)	20 Nov 2020 16:29:22
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
User entered empty.	System	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
User entered empty.	System	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:24
User entered empty.	System	19 Nov 2020 19:23:16

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:42
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	23 Nov 2020 21:38:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 21:38:54
Data point term sent to Coder	System	23 Nov 2020 16:02:38
User entered 'AZITHROMYCIN'	Russell Herstein (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'COVID-19 INFECTION'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '250'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'mg (mg)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'once daily (QD)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Oral (ORAL)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '20 Nov 2020'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '0'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Russell Herstein (b) (4)	23 Nov 2020 16:02:39
	(b) (4)	
User entered 'Yes (Y)'	Russell Herstein (b) (4)	23 Nov 2020 16:02:34
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	23 Nov 2020 16:02:39
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	23 Nov 2020 16:02:34
User entered '23 Nov 2020'	Russell Herstein (b) (4)	23 Nov 2020 16:02:34
	(b) (4)	

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
DataPoint Verified.		24 Mar 2021 21:14:57
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
User entered '1'	System	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
User entered '1'	System	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:59:30
User entered '804 (804)'	System	23 Nov 2020 16:02:34

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:12:49
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 21:38:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 21:38:22
Data point term sent to Coder	System	23 Nov 2020 16:03:40
User entered 'ACETAMINOPHEN'	Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:12:51
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:12:55
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'COVID-19 INFECTION'	Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:12:58
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '1000'	Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:13:00
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'mg (mg)'	Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:13:02
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:13:07
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'as needed (PRN)'	Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:13:09
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:13:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Oral (ORAL)'	Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:13:15
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:13:18
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '20 Nov 2020'	Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:13:21
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '0'	Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:13:23
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'Yes (Y)'	(b) (4) Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:14:30
Query 'Per the source the end date for this medication is 23NOV20 please refer to the source and update ' canceled (Site from CRA).		24 Mar 2021 21:14:27
User opened query 'Per the source the end date for this medication is 23NOV20 please refer to the source and update ' (Site from CRA).		24 Mar 2021 21:11:51
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered empty.	(b) (4) Russell Herstein (b) (4) (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:13:28
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'No (N)'	(b) (4) Russell Herstein (b) (4)	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:46:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 16:03:15

US3032110

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:46:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:55:14
User signature succeeded.	Keith Vrbicky (b) (4)	28 Sep 2020 16:57:29
User entered 'No (N)'	(b) (4) Kelsey Kelley (b) (4)	06 Aug 2020 14:11:26
	(b) (4)	

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'USA-US032-2020-MRNA-1273-P301000013'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'Keith'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'Vrbicky'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 20:06:38
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'US'	(b) (4) System	20 Nov 2020 19:55:48

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
	(b) (4)	
Signature has been broken.	System	30 Dec 2020 23:58:05
User entered '3'	System	30 Dec 2020 23:58:05
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
	(b) (4)	
Signature has been broken.	System	01 Dec 2020 20:06:48
User entered '2'	System	01 Dec 2020 20:06:48
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
	(b) (4)	
User entered '1'	System	20 Nov 2020 19:55:48

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'USA-US032-2020-MRNA-1273-P301000013'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'Keith'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'Vrbicky'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 20:06:38
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'US'	(b) (4) System	20 Nov 2020 19:55:48

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
	(b) (4)	
Signature has been broken.	System	30 Dec 2020 23:58:05
User entered '3'	System	30 Dec 2020 23:58:05
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
	(b) (4)	
Signature has been broken.	System	01 Dec 2020 20:06:48
User entered '2'	System	01 Dec 2020 20:06:48
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
	(b) (4)	
User entered '1'	System	20 Nov 2020 19:55:48

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:46:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered '20/Nov/2020 14:55'	(b) (4) System	20 Nov 2020 19:55:48

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:46:53

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)	09 Apr 2021 20:06:12
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 20:06:38
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:48

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'USA-US032-2020-MRNA-1273-P301000013'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'Keith'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'Vrbicky'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 20:06:38
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'US'	(b) (4) System	20 Nov 2020 19:55:48

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
	(b) (4)	
Signature has been broken.	System	30 Dec 2020 23:58:05
User entered '3'	System	30 Dec 2020 23:58:05
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
	(b) (4)	
Signature has been broken.	System	01 Dec 2020 20:06:48
User entered '2'	System	01 Dec 2020 20:06:48
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
	(b) (4)	
User entered '1'	System	20 Nov 2020 19:55:48

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:46:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered '01/Dec/2020 20:06'	(b) (4) System	01 Dec 2020 20:06:48

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:46:53

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)	09 Apr 2021 20:06:12
Reviewed for Safety.	(b) (4), (b) (6)	30 Dec 2020 23:57:48
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:06:48

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'USA-US032-2020-MRNA-1273-P301000013'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'No (N)'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'Keith'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 19:55:31
User entered 'Vrbicky'	System	20 Nov 2020 19:55:01

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
Reviewed for Safety.		01 Dec 2020 20:06:38
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
User entered 'US'	(b) (4) System	20 Nov 2020 19:55:48

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:46:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
	(b) (4)	
Signature has been broken.	System	30 Dec 2020 23:58:05
User entered '3'	System	30 Dec 2020 23:58:05
User signature succeeded.	Keith Vrbicky (b) (4)	08 Dec 2020 19:46:58
	(b) (4)	
Signature has been broken.	System	01 Dec 2020 20:06:48
User entered '2'	System	01 Dec 2020 20:06:48
User signature succeeded.	Keith Vrbicky (b) (4)	24 Nov 2020 20:28:23
	(b) (4)	
User entered '1'	System	20 Nov 2020 19:55:48

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:46:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
User entered '30/Dec/2020 18:58'	(b) (4) System	30 Dec 2020 23:58:05

US3032110

Folder: SAE USA-US032-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:46:53

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)	09 Apr 2021 20:06:12
User signature succeeded.	Keith Vrbicky (b) (4)	07 Jan 2021 19:15:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 23:58:05