

US3402316 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:36:03

All time stamps listed in this document are displayed in GMT

US3402316

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

[Participant ID](#)

US3402316

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

US3402316

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3402316

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	29
Age Units	YEARS
Age (Derived)	29
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

US3402316

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Date of Informed Consent (<i>dd MMM yyyy</i>)	9 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" 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

US3402316

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3402316

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Were any significant conditions reported?

Yes ☒
No ☐

US3402316

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Condition	ANXIETY
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3402316

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3402316

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Condition	BINGE EATING DISORDER
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3402316

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Condition	ALLERGY TO MORPHINE
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3402316

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 AUG 2020
Time of assessment (00:00-23:59)	11:54 (24 HR)
Vital Signs Date and Time (derived)	09 AUG 2020 11:54
Height (xxx.x)	163 cm
Weight (xxx.x)	76.3 kg
BMI (xxx.x)	28.71768 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402316

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 AUG 2020

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

US3402316

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Date of assessment (dd MMM yyyy) 09 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) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

US3402316

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	09 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3402316

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

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	

US3402316

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3402316

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

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

What was the participant's randomization number? 102480

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Height	ND - Not Done
Weight	ND - Not Done

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

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)	09 AUG 2020
Time of assessment (00:00-23:59)	11:54 (24 HR)
Vital Signs Date and Time (derived)	09 AUG 2020 11:54
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

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)	09 AUG 2020
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	09 AUG 2020 13:36
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3402316

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

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.

US3402316

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3402316

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 09 AUG 2020

What was the treatment time? (00:00-23:59) 13:05 (24 HR)

Treatment Date and Time (derived) 09 AUG 2020 13:05

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

US3402316

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 AUG 2020

Collection time (00:00-23:59)

12:20 (24 HR)

Collection date and time (derived)

09 AUG 2020 12:20

US3402316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Collection date (dd MMM yyyy)			09 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:15	09 AUG 2020 12:15
Nasopharyngeal Swab 2	No		

US3402316

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 13:41

PC Open Date & Time

09 AUG 2020 13:25

PC Close Date & Time

09 AUG 2020 15:55

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp	09 AUG 2020 22:20
PC Open Date & Time	09 AUG 2020 16:50
PC Close Date & Time	10 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

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

97.9 °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

10 AUG 2020 22:10

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 22:58

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 23:05

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 21:30

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

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

97.2 °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

15 AUG 2020 09:36

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

15 AUG 2020 21:31

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 13:42

PC Open Date & Time

09 AUG 2020 13:25

PC Close Date & Time

09 AUG 2020 15:55

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 22:20

PC Open Date & Time

09 AUG 2020 16:50

PC Close Date & Time

10 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 22:09

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

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 AUG 2020 22:57

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 23:05

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 21:30

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

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

15 AUG 2020 09:35

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

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 AUG 2020 21:30

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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

No ☒

Yes ☐

PC Time stamp	09 AUG 2020 13:42
PC Open Date & Time	09 AUG 2020 13:25
PC Close Date & Time	09 AUG 2020 15:55

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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

No ☒

Yes ☐

PC Time stamp	09 AUG 2020 22:21
PC Open Date & Time	09 AUG 2020 16:50
PC Close Date & Time	10 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

48 of 2865

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 22:09
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

50 of 2865

EAB) (1725)

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 22:57
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

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

52 of 2865

EAB) (1725)

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 23:05
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2865

EAB) (1725)

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 21:30
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

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 ☒

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 09:35
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

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 ☒

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 21:31
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3402316

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:54:54

Generated On: 11 Aug 2021 22:36:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402316

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:54:54

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:54:33

Generated On: 11 Aug 2021 22:36:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402316

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:54:33

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:54:33

Generated On: 11 Aug 2021 22:36:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402316

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:54:33

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:54:56

Generated On: 11 Aug 2021 22:36:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	11 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
------------	--------

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:54:56

Generated On: 11 Aug 2021 22:36:03

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)	11 SEP 2020
Time of assessment (00:00-23:59)	14:43 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:43
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:54:56

Generated On: 11 Aug 2021 22:36:03

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)	11 SEP 2020
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:53
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3402316

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:54:56

Generated On: 11 Aug 2021 22:36:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3402316

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:54:56

Generated On: 11 Aug 2021 22:36:03

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	11 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3402316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:54:56

Generated On: 11 Aug 2021 22:36:03

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 SEP 2020

What was the treatment time? (00:00-23:59) 15:19 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 15:19

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

What was the frequency of the study treatment dosing? ONCE

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

US3402316

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:54:56

Generated On: 11 Aug 2021 22:36:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

15:04 (24 HR)

Collection date and time (derived)

11 SEP 2020 15:04

US3402316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:54:55

Generated On: 11 Aug 2021 22:36:03

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:03	11 SEP 2020 15:03
Nasopharyngeal Swab 2	No		

US3402316

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:54:56

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 15:54

PC Open Date & Time

11 SEP 2020 15:39

PC Close Date & Time

11 SEP 2020 18:09

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

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

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

PC Time Stamp 11 SEP 2020 21:35

PC Open Date & Time 11 SEP 2020 19:04

PC Close Date & Time 12 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 22:06

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

97.8 °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

13 SEP 2020 22:05

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 20:56

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

16 SEP 2020 05:50

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 21:09

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 21:08

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 15:55

PC Open Date & Time

11 SEP 2020 15:39

PC Close Date & Time

11 SEP 2020 18:09

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 21:37

PC Open Date & Time

11 SEP 2020 19:04

PC Close Date & Time

12 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

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

12 SEP 2020 22:07

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

13 SEP 2020 22:05

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

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

14 SEP 2020 20:57

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

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

16 SEP 2020 05:50

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

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

16 SEP 2020 21:09

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

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

17 SEP 2020 21:08

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 15:55
PC Open Date & Time	11 SEP 2020 15:39
PC Close Date & Time	11 SEP 2020 18:09

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 21:36
PC Open Date & Time	11 SEP 2020 19:04
PC Close Date & Time	12 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

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 ☒

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 22:06
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

97 of 2865

EAB) (1725)

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 22:06
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

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

99 of 2865

EAB) (1725)

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 20:57
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

101 of 2865

EAB) (1725)

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 05:50
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

103 of 2865

EAB) (1725)

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 21:09
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

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)

105 of 2865

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 21:08
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

18 SEP 2020 22:27

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 20 SEP 2020 09:37

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 SEP 2020 22:28
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3402316

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 SEP 2020 09:37
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3402316

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:54:33

Generated On: 11 Aug 2021 22:36:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402316

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:54:33

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:54:33

Generated On: 11 Aug 2021 22:36:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402316

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:54:33

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:54:54

Generated On: 11 Aug 2021 22:36:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402316

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:54:33

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:54:56

Generated On: 11 Aug 2021 22:36:03

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3402316

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:54:56

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	09 OCT 2020 05:14:11
Patient Cloud Open Date & Time	09 OCT 2020 00:01
Patient Cloud Close Date & Time	13 OCT 2020 23:59

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 <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	16 OCT 2020 00:01:50
Patient Cloud Open Date & Time	16 OCT 2020 00:01
Patient Cloud Close Date & Time	20 OCT 2020 23:59

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 OCT 2020 07:09:25
Patient Cloud Open Date & Time	23 OCT 2020 00:01
Patient Cloud Close Date & Time	27 OCT 2020 23:59

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 11:59:14

Patient Cloud Open Date & Time

06 NOV 2020 00:01

Patient Cloud Close Date & Time

10 NOV 2020 23:59

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 <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	14 NOV 2020 08:13:46
Patient Cloud Open Date & Time	13 NOV 2020 00:01
Patient Cloud Close Date & Time	17 NOV 2020 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2020 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2020 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 DEC 2020 12:36:51
Patient Cloud Open Date & Time	01 DEC 2020 00:01
Patient Cloud Close Date & Time	05 DEC 2020 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 05:55:05
Patient Cloud Open Date & Time	08 DEC 2020 00:01
Patient Cloud Close Date & Time	12 DEC 2020 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

17 DEC 2020 12:00:39

Patient Cloud Open Date & Time

15 DEC 2020 00:01

Patient Cloud Close Date & Time

19 DEC 2020 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

25 DEC 2020 18:20:04

Patient Cloud Open Date & Time

22 DEC 2020 00:01

Patient Cloud Close Date & Time

26 DEC 2020 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 145

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 19:22:40

Patient Cloud Open Date & Time

05 JAN 2021 00:01

Patient Cloud Close Date & Time

09 JAN 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

14 JAN 2021 12:00:27

Patient Cloud Open Date & Time

12 JAN 2021 00:01

Patient Cloud Close Date & Time

16 JAN 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 166

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 12:00:14
Patient Cloud Open Date & Time	02 FEB 2021 00:01
Patient Cloud Close Date & Time	06 FEB 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

13 FEB 2021 11:59:19

Patient Cloud Open Date & Time

09 FEB 2021 00:01

Patient Cloud Close Date & Time

13 FEB 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 17:59:38

Patient Cloud Open Date & Time

16 FEB 2021 00:01

Patient Cloud Close Date & Time

20 FEB 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 17:34:47

Patient Cloud Open Date & Time

23 FEB 2021 00:01

Patient Cloud Close Date & Time

27 FEB 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 12:00:50

Patient Cloud Open Date & Time

02 MAR 2021 00:01

Patient Cloud Close Date & Time

06 MAR 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

13 MAR 2021 12:09:17

Patient Cloud Open Date & Time

09 MAR 2021 00:01

Patient Cloud Close Date & Time

13 MAR 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

16 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

25 MAR 2021 12:00:22

Patient Cloud Open Date & Time

23 MAR 2021 00:01

Patient Cloud Close Date & Time

27 MAR 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

01 APR 2021 13:07:48

Patient Cloud Open Date & Time

30 MAR 2021 00:01

Patient Cloud Close Date & Time

03 APR 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 243

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

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

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

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

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

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

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 12:17:14
Patient Cloud Open Date & Time	13 APR 2021 00:01
Patient Cloud Close Date & Time	17 APR 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 APR 2021 18:11:46
Patient Cloud Open Date & Time	20 APR 2021 00:01
Patient Cloud Close Date & Time	24 APR 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

29 APR 2021 12:16:25

Patient Cloud Open Date & Time

27 APR 2021 00:01

Patient Cloud Close Date & Time

01 MAY 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

18 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

01 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 <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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

06 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

03 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 <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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

[Patient Cloud Close Date & Time](#)

11 SEP 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

14 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

21 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

[Patient Cloud Close Date & Time](#)

23 OCT 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

30 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	11 DEC 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

18 DEC 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	21 DEC 2021 00:01
Patient Cloud Close Date & Time	25 DEC 2021 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

11 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JAN 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

01 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

05 FEB 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

08 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

12 FEB 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

19 FEB 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	22 FEB 2022 00:01
Patient Cloud Close Date & Time	26 FEB 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAR 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

08 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAR 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

15 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAR 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

22 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 <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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 APR 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 APR 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

17 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

31 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

21 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

05 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

23 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 <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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 <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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 <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"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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

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

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	11 OCT 2022 00:01
Patient Cloud Close Date & Time	15 OCT 2022 23:59

US3402316

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:36:03

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		04 MAR 2021 12:00:45

US3402316

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:26:23

Generated On: 11 Aug 2021 22:36:03

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

SUBJECT IN CONVALESCENT
PHASE

If Contact Not Made, please provide Comments

US3402316

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:26:23

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402316

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402316

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	24 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:09:54

Generated On: 11 Aug 2021 22:36:03

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) _____

US3402316

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3402316

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	24 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	15:25 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	24 FEB 2021 15:25
------------------------------------	-------------------

US3402316

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402316

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402316

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

Date of Contact	14 OCT 2020
Time of Contact	14:00
Date and Time of Contact (derived)	14 OCT 2020 14:00
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

327 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

328 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

335 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

339 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.5 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

343 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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

344 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.7 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

347 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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

348 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.5 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

351 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

355 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

359 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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

360 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

363 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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

364 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

367 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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

368 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

371 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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

372 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

375 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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)

380 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

387 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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)

388 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

391 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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	31 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

395 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

399 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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)

400 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		403 of 2865
EAB) (1725)		

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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	03 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

407 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

411 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 type="checkbox"/>
Day 23	<input checked="" 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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

415 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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)

416 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input checked="" 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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

419 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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)

420 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input checked="" 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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

423 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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)

424 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input checked="" 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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

427 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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)

428 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 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 checked="" 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"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		431 of 2865
EAB) (1725)		

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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)

432 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 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 checked="" type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.7 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		435 of 2865
EAB) (1725)		

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

	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)

436 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

Date of Visit	14 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	14 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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 _____

End Date _____

Oxygen Saturation _____

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 _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

439 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

440 of 2865

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 OCT 2020
Day 5	Yes	18 OCT 2020
Day 7	Yes	20 OCT 2020
Day 9	Yes	22 OCT 2020
Day 14	Yes	27 OCT 2020
Day 21	Yes	03 NOV 2020
Day 28	Yes	10 NOV 2020

US3402316

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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	SICKD1

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 14:00
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3402316

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 OCT 2020

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	SICKD28

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 NOV 2020
Time of assessment (00:00-23:59)	15:26 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 15:26
Height (xxx.x)	163.4 cm
Weight (xxx.x)	83.2 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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 NOV 2020

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

US3402316

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 26 Apr 2021 23:09:51

Generated On: 11 Aug 2021 22:36:03

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 NOV 2020

US3402316

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	24 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3402316

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Date of updated informed consent (dd MMM yyyy) 06 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 24 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3402316

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 FEB 2021

Collection time (00:00-23:59)

15:25 (24 HR)

Collection date and time (derived)

24 FEB 2021 15:25

US3402316

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 FEB 2021

Collection time (00:00 - 23:59)

15:23

Collection Date and Time (derived)

24 FEB 2021 15:23

US3402316

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:45:41

Generated On: 11 Aug 2021 22:36:03

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

EAB) (1725)

457 of 2865

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

AEID	USA-US059-2020-MRNA-1273-P30 1000008
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)	12 OCT 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)	26 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input 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)

459 of 2865

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

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

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

SUBJECTHAD DIRECT
EXPOSURE TO A PERSON WITH
A POSITIVE COVID 19
DIAGNOSIS. THEY WERE
BROUGHT IN FOR AN ILLNESS
VISIT DUE TO SYMPTOMS.
SUBJECT DID NOT USE ANY
MEDICATION TO TREAT
SYMPTOMS

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)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

AEID	
Adverse event	PREGNANCY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

462 of 2865

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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)	_____

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

AEID

Adverse event FATIGUE

Was this a medically-attended AE? Yes ☐
No ☒

Was this a Solicited Adverse Reaction? Yes ☒
No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 11 SEP 2020

Start time (00:00-23:59) 05:00 (24 HR)

AE start date and time (derived) 11 SEP 2020 05:00

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 20 SEP 2020

End time (00:00-23:59) 17:30 (24 HR)

AE End Date and Time (derived) 20 SEP 2020 17:30

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

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

464 of 2865

EAB) (1725)

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

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

Yes ☒

No ☐

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

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

Name of Medication WELLBUTRIN XL

Prophylaxis Yes ☐
No ☒

Indication ANXIETY AND DEPRESSION

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

467 of 2865

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

	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 DEC 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"/>

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

Name of Medication CELEXA

Prophylaxis Yes ☐
No ☒

Indication ANXIETY AND DEPRESSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

469 of 2865

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

471 of 2865

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

	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)		10 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)		10 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"/>

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

Name of Medication CIPRO

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT 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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

473 of 2865

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 16 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

475 of 2865

EAB) (1725)

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 SEP 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 checked="" type="radio"/>
	No	<input type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

Name of Medication NUVARING

Prophylaxis Yes ☒
No ☐

Indication BIRTH CONTROL

Dose per administration 11.7/2.7

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

477 of 2865

EAB) (1725)

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input checked="" type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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 checked="" type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3402316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:37:46

Generated On: 11 Aug 2021 22:36:03

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3402316

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:36:03

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3402316

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:36:03

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 ☐

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

SAEID	USA-US059-2020-MRNA-1273-P301000008
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

SAEID	USA-US059-2020-MRNA-1273-P301000008
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/OCT/2020 17:30
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

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

SAEID	USA-US059-2020-MRNA-1273-P301000008
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/OCT/2020 19:00
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

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

SAEID	USA-US059-2020-MRNA-1273-P301000008
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/OCT/2020 16:28
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

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

SAEID	USA-US059-2020-MRNA-1273-P301000008
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/NOV/2020 17:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

SAEID	USA-US059-2020-MRNA-1273-P301000011
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 23:09:53

Generated On: 11 Aug 2021 22:36:03

SAEID	USA-US059-2020-MRNA-1273-P301000011
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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	26/OCT/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

US3402316 (Prod: Meridian Clinical Research, LLC)

US3402316

Form: Participant Creation

Generated On: 11 Aug 2021 22:36:03

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'US3402316'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 16:09:06

US3402316

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4)	
	Jennifer Molstead (b) (4)	09 Aug 2020 17:38:20
	(b) (4)	

US3402316

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '09 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 16:09:07

US3402316

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Clinic (Clinic)'	(b) (4) Jennifer Molstead (b) (4)	09 Aug 2020 17:38:20

US3402316

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'SCRN'	System	09 Aug 2020 17:38:20

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered (b) (6) 1990'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 16:09:08

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '29'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:44:51

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'YEARS'	System	10 Aug 2020 20:44:51

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered '29'	System	09 Aug 2020 17:38:36

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Female (F)'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:44:51

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:44:51

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'I'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:44:51

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:44:51

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:44:51
	(b) (4)	

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:44:51

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:44:51

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:44:51

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:44:51

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:44:51

US3402316

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:03

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:44:51

US3402316

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '9 Aug 2020'	(b) (4) Jennifer Molstead (b) (4)	09 Aug 2020 17:38:36

US3402316

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'Aug 2020'	System	09 Aug 2020 17:38:36

US3402316

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered '2020'	System	09 Aug 2020 17:38:36

US3402316

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Amendment 2 (2)'	(b) (4) Jennifer Molstead (b) (4)	09 Aug 2020 17:38:36

US3402316

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Jennifer Molstead (b) (4)	09 Aug 2020 17:38:36

US3402316

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:03

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4)	Jennifer Molstead (b) (4) 09 Aug 2020 17:38:36
	(b) (4)	

US3402316

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4)	Jennifer Molstead (b) (4) 09 Aug 2020 17:38:36
	(b) (4)	

US3402316

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	(b) (4)	
	Jennifer Molstead (b) (4)	09 Aug 2020 17:38:36
	(b) (4)	

US3402316

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 16:09:07

US3402316

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'I'	System	09 Aug 2020 17:38:42

US3402316

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4)	Jennifer Molstead (b) (4) 09 Aug 2020 17:38:42
	(b) (4)	

US3402316

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:36:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	10 Aug 2020 20:45:31
	(b) (4)	

US3402316

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	11 Aug 2020 22:29:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:07
Data point term sent to Coder	System	10 Aug 2020 20:46:34
User entered 'ANXIETY'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:45:53

US3402316

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'UN Dec 2019' reason for change: Per Query Resolution	(b) (4)	23 Sep 2020 18:32:59
User entered 'UN Mar 2020'	Traci Hull (b) (4)	10 Aug 2020 20:45:53
	(b) (4)	

US3402316

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:45:53

US3402316

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:45:53

US3402316

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:45:53
	(b) (4)	

US3402316

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:45:53

US3402316

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'Dec 2019'	System	23 Sep 2020 18:32:59
User entered 'Mar 2020'	System	10 Aug 2020 20:45:53

US3402316

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered '2019'	System	23 Sep 2020 18:32:59
User entered '2020'	System	10 Aug 2020 20:45:53

US3402316

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered empty.	System	10 Aug 2020 20:45:53

US3402316

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered empty.	System	10 Aug 2020 20:45:53

US3402316

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:50
Data point term sent to Coder	(b) (4)	
User entered 'DEPRESSION'	System	10 Aug 2020 20:46:36
	Traci Hull (b) (4)	10 Aug 2020 20:46:05
	(b) (4)	

US3402316

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'UN Dec 2019' reason for change: Per Query Resolution	(b) (4)	23 Sep 2020 18:33:14
User entered 'UN Mar 2020'	Traci Hull (b) (4)	10 Aug 2020 20:46:05
	(b) (4)	

US3402316

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:46:05

US3402316

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:46:05

US3402316

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:46:05

US3402316

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:46:05

US3402316

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'Dec 2019'	System	23 Sep 2020 18:33:14
User entered 'Mar 2020'	System	10 Aug 2020 20:46:05

US3402316

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered '2019'	System	23 Sep 2020 18:33:14
User entered '2020'	System	10 Aug 2020 20:46:05

US3402316

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered empty.	System	10 Aug 2020 20:46:05

US3402316

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered empty.	System	10 Aug 2020 20:46:05

US3402316

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User coded data point as SOC: Psychiatric disorders, HLGT: Eating disorders and disturbances, HLT: Eating disorders NEC, PT: Binge eating, LLT: Binge eating - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 22:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:39
Data point term sent to Coder	System	10 Aug 2020 20:46:37
User entered 'BINGE EATING DISORDER'	Traci Hull (b) (4)	10 Aug 2020 20:46:30
	(b) (4)	

US3402316

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'UN UNK 2000'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:46:30

US3402316

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:46:30

US3402316

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:46:30

US3402316

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:46:30

US3402316

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:46:30

US3402316

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'Jan 2000'	System	10 Aug 2020 20:46:30

US3402316

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered '2000'	System	10 Aug 2020 20:46:30

US3402316

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered empty.	System	10 Aug 2020 20:46:30

US3402316

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered empty.	System	10 Aug 2020 20:46:30

US3402316

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 22:29:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:29:00
Data point term sent to Coder	System	10 Aug 2020 20:47:38
User entered 'ALLERGY TO MORPHINE'	Traci Hull (b) (4)	10 Aug 2020 20:46:42
	(b) (4)	

US3402316

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'UN UNK 2015'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:46:42

US3402316

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:46:42

US3402316

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:46:42

US3402316

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:46:42

US3402316

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:46:42

US3402316

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'Jan 2015'	System	10 Aug 2020 20:46:42

US3402316

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered '2015'	System	10 Aug 2020 20:46:42

US3402316

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered empty.	System	10 Aug 2020 20:46:42

US3402316

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered empty.	System	10 Aug 2020 20:46:42

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:47:35

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '09 Aug 2020' reason for change: New Information	(b) (4)	11 Nov 2020 14:35:19
User entered '9 Aug 2020'	Traci Hull (b) (4)	10 Aug 2020 20:47:35
	(b) (4)	

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '11:54'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:47:35

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered '09 Aug 2020 11:54'	System	11 Nov 2020 14:35:19
User entered '9 Aug 2020 11:54'	System	10 Aug 2020 20:47:35

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '163' cm	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:47:35
DataPoint set to visible.	(b) (4) System	09 Aug 2020 17:38:42

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '76.3' kg	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:47:35
DataPoint set to visible.	(b) (4) System	09 Aug 2020 17:38:42

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
Amendment Manager: User entered '28.71768'	System	16 Sep 2020 23:49:18
User entered '28.7'	System	10 Aug 2020 20:47:35
DataPoint set to visible.	System	09 Aug 2020 17:38:42

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'kg/m2'	System	10 Aug 2020 20:47:35
DataPoint set to visible.	System	09 Aug 2020 17:38:42

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	26 Oct 2020 19:47:49
User entered missing code ND - Not Done; reason for change Data Entry Error	System	26 Oct 2020 19:47:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Tammy Kohn (b) (4)	26 Oct 2020 19:47:38
User entered 'NS' (non-conformant).	(b) (4)	26 Oct 2020 19:47:38
User entered '98.3' F	Tammy Kohn (b) (4)	26 Oct 2020 19:47:38
	(b) (4)	10 Aug 2020 20:47:35
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty; reason for change Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	26 Oct 2020 19:47:38
	(b) (4)	
User entered 'Oral (Oral)'	Traci Hull (b) (4)	10 Aug 2020 20:47:35
	(b) (4)	

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:47:35

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 19:47:38
User entered '72'	Tammy Kohn (b) (4)	26 Oct 2020 19:47:38
	(b) (4)	
	Traci Hull (b) (4)	10 Aug 2020 20:47:35
	(b) (4)	

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'bpm'	System	10 Aug 2020 20:47:35

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 19:47:38
User entered '14'	Tammy Kohn (b) (4)	26 Oct 2020 19:47:38
	(b) (4)	
	Traci Hull (b) (4)	10 Aug 2020 20:47:35
	(b) (4)	

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'breaths/min'	System	10 Aug 2020 20:47:35

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 19:47:38
User entered '104'	Tammy Kohn (b) (4)	26 Oct 2020 19:47:38
	(b) (4)	
	Traci Hull (b) (4)	10 Aug 2020 20:47:35
	(b) (4)	

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'mmHg'	System	10 Aug 2020 20:47:35

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 19:47:38
User entered '64'	Tammy Kohn (b) (4)	26 Oct 2020 19:47:38
	(b) (4)	
	Traci Hull (b) (4)	10 Aug 2020 20:47:35
	(b) (4)	

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered 'mmHg'	System	10 Aug 2020 20:47:35

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58

US3402316

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58

US3402316

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:47:46

US3402316

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '09 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 14:35:31
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 22:35:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		11 Sep 2020 19:28:41
User entered '9 Aug 2020'	Traci Hull (b) (4)	10 Aug 2020 20:47:46

US3402316

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:36:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '09 Aug 2020' reason for change: New Information	(b) (4)	11 Nov 2020 14:35:53
User entered '9 Aug 2020'	Traci Hull (b) (4)	10 Aug 2020 20:48:19
	(b) (4)	

US3402316

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:36:03

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:48:19

US3402316

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:36:03

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:48:19

US3402316

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:36:03

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:48:19

US3402316

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:48:19

US3402316

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:36:03

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:48:19

US3402316

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:48:19

US3402316

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:36:03

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:48:19

US3402316

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:48:43

US3402316

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '09 Aug 2020' reason for change: New Information	(b) (4)	11 Nov 2020 14:36:03
User entered '9 Aug 2020'	Traci Hull (b) (4)	10 Aug 2020 20:48:43
	(b) (4)	

US3402316

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Urine (URINE)'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:48:43

US3402316

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Negative (NEGATIVE)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:48:43

US3402316

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	10 Aug 2020 20:48:43
	(b) (4)	

US3402316

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:48:43

US3402316

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:48:43

US3402316

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User entered empty.	System	10 Aug 2020 20:48:43

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:45:16
	(b) (4)	

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:45:16
	(b) (4)	

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:45:16
	(b) (4)	

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:45:16
	(b) (4)	

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	Traci Hull (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	Traci Hull (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'I'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:45:16

US3402316

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:58
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:45:16
	(b) (4)	

US3402316

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Traci Hull (b) (4)	10 Aug 2020 20:48:58

US3402316

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '09 Aug 2020' reason for change: New Information	(b) (4)	11 Nov 2020 14:36:21
User entered '9 Aug 2020'	Traci Hull (b) (4)	10 Aug 2020 20:48:58
	(b) (4)	

US3402316

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	10 Aug 2020 20:48:58

US3402316

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'VISIT1'	System	10 Aug 2020 20:48:58

US3402316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '09 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 16:39:07

US3402316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:03

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 03:11:06
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:11:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Aug 2020 16:39:07
User entered '102480' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	09 Aug 2020 16:39:07

US3402316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:03

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '>=18 and <65 years and not at risk (1)'	(b) (4)	09 Aug 2020 16:39:07
	RWS_ENDPOINT ENDPOINT (b) (4)	

US3402316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:03

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 20:49:08

US3402316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:03

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 20:49:08

US3402316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:03

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 20:49:08

US3402316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:03

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:49:08

US3402316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 20:49:08

US3402316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:03

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	Tammy Kohn (b) (4)	26 Oct 2020 19:46:38
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:04:15
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:41:12

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 19:47:01
User entered '163' cm	Tammy Kohn (b) (4)	10 Aug 2020 20:50:38
	(b) (4)	

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 19:47:01
User entered '76.3' kg	Tammy Kohn (b) (4)	26 Oct 2020 19:47:01
	(b) (4)	
	Traci Hull (b) (4)	10 Aug 2020 20:50:38
	(b) (4)	

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 19:47:01
User entered '163' cm	Tammy Kohn (b) (4)	10 Aug 2020 20:50:38
	(b) (4)	

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 19:47:01
User entered '76.3' kg	Tammy Kohn (b) (4)	26 Oct 2020 19:47:01
	(b) (4)	
	Traci Hull (b) (4)	10 Aug 2020 20:50:38
	(b) (4)	

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '09 Aug 2020' reason for change: New Information	(b) (4)	11 Nov 2020 14:36:46
User entered '9 Aug 2020'	Traci Hull (b) (4)	10 Aug 2020 20:50:38
	(b) (4)	

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '11:54'	(b) (4)	10 Aug 2020 20:50:38
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered '09 Aug 2020 11:54'	System	11 Nov 2020 14:36:46
User entered '9 Aug 2020 11:54'	System	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '98.3' F	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '72'	Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'bpm'	System	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '14'	Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'breaths/min'	System	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '104'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'mmHg'	System	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '64'	Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'mmHg'	System	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 19:47:01
User entered '163' cm	Tammy Kohn (b) (4)	10 Aug 2020 20:50:38
	(b) (4)	

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 19:47:01
User entered '76.3' kg	Tammy Kohn (b) (4)	26 Oct 2020 19:47:01
	(b) (4)	
	Traci Hull (b) (4)	10 Aug 2020 20:50:38
	(b) (4)	

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '09 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 14:36:46
User entered '9 Aug 2020'	Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
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)	14 Aug 2020 13:31:57
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 MINUTE' (Site from System).	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:50:48
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).		10 Aug 2020 20:50:38
User entered '13:36'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered '09 Aug 2020 13:36'	System	11 Nov 2020 14:36:46
User entered '9 Aug 2020 13:36'	System	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '97.5' F	Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '74'	Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'bpm'	System	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '14'	Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'breaths/min'	System	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '98'	Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'mmHg'	System	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '60'	Traci Hull (b) (4)	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'mmHg'	System	10 Aug 2020 20:50:38

US3402316

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	18 Sep 2020 17:01:18
User entered 'Yes (Y)'	Traci Hull (b) (4)	10 Aug 2020 20:51:06

US3402316

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	18 Sep 2020 17:01:18
User entered '9 Aug 2020'	Traci Hull (b) (4)	10 Aug 2020 20:51:06

US3402316

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	18 Sep 2020 17:01:49
User entered 'Yes (Y)'	Traci Hull (b) (4)	10 Aug 2020 20:51:51

US3402316

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	18 Sep 2020 17:01:49
User entered '9 Aug 2020'	Traci Hull (b) (4)	10 Aug 2020 20:51:51

US3402316

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	18 Sep 2020 17:01:49
User entered 'Urine (URINE)'	Traci Hull (b) (4)	10 Aug 2020 20:51:51

US3402316

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	18 Sep 2020 17:01:49
User entered 'Negative (NEGATIVE)'	Traci Hull (b) (4)	10 Aug 2020 20:51:51

US3402316

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User closed query 'Per CDM: A response Yes/No is required for this field. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 10:37:13
Query 'Per CDM: A response Yes/No is required for this field. Please update accordingly' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Nov 2020 13:25:28
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Nov 2020 13:25:18
User opened query 'Per CDM: A response Yes/No is required for this field. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:12:58
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Sep 2020 17:01:49
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:51:51

US3402316

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4)	10 Aug 2020 20:51:51
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Aug 2020 20:51:51

US3402316

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered empty.	System	10 Aug 2020 20:51:51

US3402316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Aug 2020 17:39:08

US3402316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	Jennifer Molstead (b) (4)	09 Aug 2020 17:39:08

US3402316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	Jennifer Molstead (b) (4)	09 Aug 2020 17:39:08

US3402316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'MRNA-1273 OR PLACEBO'	System	09 Aug 2020 17:39:08

US3402316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '09 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 14:37:06
User entered '9 Aug 2020'	Jennifer Molstead (b) (4)	09 Aug 2020 17:39:08

US3402316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '13:05'	Jennifer Molstead (b) (4)	09 Aug 2020 17:39:08

US3402316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered '09 Aug 2020 13:05'	System	11 Nov 2020 14:37:06
User entered '9 Aug 2020 13:05'	System	09 Aug 2020 17:39:08

US3402316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	09 Aug 2020 17:39:08

US3402316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'ONCE'	System	09 Aug 2020 17:39:08

US3402316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'INTRAMUSCULAR'	System	09 Aug 2020 17:39:08

US3402316

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Traci Hull (b) (4)	10 Aug 2020 20:53:00

US3402316

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '09 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 14:37:17
User entered '9 Aug 2020'	Traci Hull (b) (4)	10 Aug 2020 20:53:00

US3402316

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '12:20'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:53:00

US3402316

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered '09 Aug 2020 12:20'	System	11 Nov 2020 14:37:17
User entered '9 Aug 2020 12:20'	System	10 Aug 2020 20:53:00

US3402316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:36:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '09 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 14:37:28
User entered '9 Aug 2020'	Traci Hull (b) (4)	10 Aug 2020 20:53:29

US3402316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:53:29

US3402316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:53:29

US3402316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '12:15'	Traci Hull (b) (4)	10 Aug 2020 20:53:29

US3402316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered '09 Aug 2020 12:15'	System	11 Nov 2020 14:37:28
User entered '9 Aug 2020 12:15'	System	10 Aug 2020 20:53:29

US3402316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:53:29

US3402316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:53:29

US3402316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:03

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	Traci Hull (b) (4)	10 Aug 2020 20:53:29

US3402316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered empty.	System	10 Aug 2020 20:53:29

US3402316

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Traci Hull (b) (4)	10 Aug 2020 20:53:37

US3402316

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'I'	System	10 Aug 2020 20:53:37

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:41:40', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'e006f62b-b514-4b8b-95d9-ecf90983941b' User entered 'Yes (Y)'	System	09 Aug 2020 17:41:58
	System	09 Aug 2020 17:41:58

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:41:48', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'e006f62b-b514-4b8b-95d9-ecf90983941b' User entered '97.5'	System	09 Aug 2020 17:41:58
	System	09 Aug 2020 17:41:58

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:41:52', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'e006f62b-b514-4b8b-95d9-ecf90983941b' User entered 'No (N)'	System	09 Aug 2020 17:41:58
	System	09 Aug 2020 17:41:58

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:41:55', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'e006f62b-b514-4b8b-95d9-ecf90983941b' User entered '09 Aug 2020 13:41'	System	09 Aug 2020 17:41:58
	System	09 Aug 2020 17:41:58

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '09 Aug 2020 13:25'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '09 Aug 2020 15:55'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 1, after vaccination (at home)'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:19:27', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '351f9363-249a-4b15-8d74-80e4695645fd' User entered 'Yes (Y)'	System	10 Aug 2020 02:20:19
	System	10 Aug 2020 02:20:19

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:20:08', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '351f9363-249a-4b15-8d74-80e4695645fd' User entered '97.5'	System	10 Aug 2020 02:20:19
	System	10 Aug 2020 02:20:19

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:20:12', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '351f9363-249a-4b15-8d74-80e4695645fd' User entered 'No (N)'	System	10 Aug 2020 02:20:19
	System	10 Aug 2020 02:20:19

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:20:17', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '351f9363-249a-4b15-8d74-80e4695645fd' User entered '09 Aug 2020 22:20'	System	10 Aug 2020 02:20:19
	System	10 Aug 2020 02:20:19

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '09 Aug 2020 16:50'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '10 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 2'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:09:50', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f062dbf6-8b01-4a87-bdc7-c6a8d1142431' User entered 'Yes (Y)'	System	11 Aug 2020 02:10:27
	System	11 Aug 2020 02:10:27

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:10:16', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f062dbf6-8b01-4a87-bdc7-c6a8d1142431' User entered '97.9'	System	11 Aug 2020 02:10:27
	System	11 Aug 2020 02:10:27

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:10:21', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f062dbf6-8b01-4a87-bdc7-c6a8d1142431' User entered 'No (N)'	System	11 Aug 2020 02:10:27
	System	11 Aug 2020 02:10:27

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:10:26', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f062dbf6-8b01-4a87-bdc7-c6a8d1142431' User entered '10 Aug 2020 22:10'	System	11 Aug 2020 02:10:27
	System	11 Aug 2020 02:10:27

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 3'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:58:33', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'fef9295d-eab1-4fd0-94a7-d7ea2a693e6c' User entered 'Yes (Y)'	System	12 Aug 2020 02:58:47
	System	12 Aug 2020 02:58:47

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:58:38', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'fef9295d-eab1-4fd0-94a7-d7ea2a693e6c' User entered '97.1'	System	12 Aug 2020 02:58:47
	System	12 Aug 2020 02:58:47

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:58:41', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'fef9295d-eab1-4fd0-94a7-d7ea2a693e6c' User entered 'No (N)'	System	12 Aug 2020 02:58:47
	System	12 Aug 2020 02:58:47

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:58:44', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'fef9295d-eab1-4fd0-94a7-d7ea2a693e6c' User entered '11 Aug 2020 22:58'	System	12 Aug 2020 02:58:47
	System	12 Aug 2020 02:58:47

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 4'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:04:51', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '84a637d2-25b7-443b-9834-b5c0d512ac3e' User entered 'Yes (Y)'	System	13 Aug 2020 03:05:07
	System	13 Aug 2020 03:05:07

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:04:59', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '84a637d2-25b7-443b-9834-b5c0d512ac3e' User entered '97.5'	System	13 Aug 2020 03:05:07
	System	13 Aug 2020 03:05:07

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:01', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '84a637d2-25b7-443b-9834-b5c0d512ac3e' User entered 'No (N)'	System	13 Aug 2020 03:05:07

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:04', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '84a637d2-25b7-443b-9834-b5c0d512ac3e' User entered '12 Aug 2020 23:05'	System	13 Aug 2020 03:05:07
	System	13 Aug 2020 03:05:07

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '12 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '13 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 5'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:40', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '780da670-2ba8-4329-b809-b5e9af92c02f' User entered 'Yes (Y)'	System	14 Aug 2020 01:30:52
	System	14 Aug 2020 01:30:52

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:45', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '780da670-2ba8-4329-b809-b5e9af92c02f' User entered '98.0'	System	14 Aug 2020 01:30:52
	System	14 Aug 2020 01:30:52

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:48', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '780da670-2ba8-4329-b809-b5e9af92c02f' User entered 'No (N)'	System	14 Aug 2020 01:30:52
	System	14 Aug 2020 01:30:52

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:51', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '780da670-2ba8-4329-b809-b5e9af92c02f' User entered '13 Aug 2020 21:30'	System	14 Aug 2020 01:30:52
	System	14 Aug 2020 01:30:52

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '13 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '14 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 6'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:59', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '573a27cd-cb7a-4b0c-94a5-336d46ae7170' User entered 'Yes (Y)'	System	15 Aug 2020 13:36:35
	System	15 Aug 2020 13:36:35

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:36:23', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '573a27cd-cb7a-4b0c-94a5-336d46ae7170' User entered '97.2'	System	15 Aug 2020 13:36:35
	System	15 Aug 2020 13:36:35

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:36:31', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '573a27cd-cb7a-4b0c-94a5-336d46ae7170' User entered 'No (N)'	System	15 Aug 2020 13:36:35
	System	15 Aug 2020 13:36:35

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:36:33', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '573a27cd-cb7a-4b0c-94a5-336d46ae7170' User entered '15 Aug 2020 09:36'	System	15 Aug 2020 13:36:35
	System	15 Aug 2020 13:36:35

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '14 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '15 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 7'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:31:15', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'c3e6cb58-ca1c-48c8-b712-d7b8f1d3ca8c' User entered 'Yes (Y)'	System	16 Aug 2020 01:31:26
	System	16 Aug 2020 01:31:26

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:31:18', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'c3e6cb58-ca1c-48c8-b712-d7b8f1d3ca8c' User entered '97.9'	System	16 Aug 2020 01:31:26
	System	16 Aug 2020 01:31:26

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:31:20', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'c3e6cb58-ca1c-48c8-b712-d7b8f1d3ca8c'	System	16 Aug 2020 01:31:26
User entered 'No (N)'	System	16 Aug 2020 01:31:26

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:31:22', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'c3e6cb58-ca1c-48c8-b712-d7b8f1d3ca8c' User entered '15 Aug 2020 21:31'	System	16 Aug 2020 01:31:26
	System	16 Aug 2020 01:31:26

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '15 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '16 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:05', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '85f4ce65-ef25-48b4-9647-1eb580d0db79'	System	09 Aug 2020 17:42:24
User entered 'None (1)'	System	09 Aug 2020 17:42:24

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:12', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '85f4ce65-ef25-48b4-9647-1eb580d0db79'	System	09 Aug 2020 17:42:24
User entered 'No (N)'	System	09 Aug 2020 17:42:24

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:15', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '85f4ce65-ef25-48b4-9647-1eb580d0db79'	System	09 Aug 2020 17:42:24
User entered 'No (N)'	System	09 Aug 2020 17:42:24

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:19', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '85f4ce65-ef25-48b4-9647-1eb580d0db79'	System	09 Aug 2020 17:42:24
User entered 'None (1)'	System	09 Aug 2020 17:42:24

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:22', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '85f4ce65-ef25-48b4-9647-1eb580d0db79' User entered '09 Aug 2020 13:42'	System	09 Aug 2020 17:42:24
	System	09 Aug 2020 17:42:24

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '09 Aug 2020 13:25'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '09 Aug 2020 15:55'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 1, after vaccination (at home)'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:20:26', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '300e14b9-da93-4200-8691-18a19234f4c3'	System	10 Aug 2020 02:21:01
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 02:21:01

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:20:35', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '300e14b9-da93-4200-8691-18a19234f4c3' User entered 'No (N)'	System	10 Aug 2020 02:21:01
	System	10 Aug 2020 02:21:01

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:20:42', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '300e14b9-da93-4200-8691-18a19234f4c3' User entered 'No (N)'	System	10 Aug 2020 02:21:01
	System	10 Aug 2020 02:21:01

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:20:55', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '300e14b9-da93-4200-8691-18a19234f4c3' User entered 'None (1)'	System	10 Aug 2020 02:21:01
	System	10 Aug 2020 02:21:01

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:20:58', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '300e14b9-da93-4200-8691-18a19234f4c3' User entered '09 Aug 2020 22:20'	System	10 Aug 2020 02:21:01
	System	10 Aug 2020 02:21:01

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '09 Aug 2020 16:50'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '10 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 2'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:08:52', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9fb6c232-3b59-48a2-94b6-10c4aa13018f' User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 02:09:09
	System	11 Aug 2020 02:09:09

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:08:56', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9fb6c232-3b59-48a2-94b6-10c4aa13018f' User entered 'No (N)'	System	11 Aug 2020 02:09:09
	System	11 Aug 2020 02:09:09

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:08:59', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9fb6c232-3b59-48a2-94b6-10c4aa13018f' User entered 'No (N)'	System	11 Aug 2020 02:09:09
	System	11 Aug 2020 02:09:09

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:09:02', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9fb6c232-3b59-48a2-94b6-10c4aa13018f' User entered 'None (1)'	System	11 Aug 2020 02:09:09
	System	11 Aug 2020 02:09:09

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:09:06', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9fb6c232-3b59-48a2-94b6-10c4aa13018f' User entered '10 Aug 2020 22:09'	System	11 Aug 2020 02:09:09
	System	11 Aug 2020 02:09:09

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 3'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:42', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f031ae03-edb2-44f7-aa79-7dc2835673b0' User entered 'None (1)'	System	12 Aug 2020 02:57:56
	System	12 Aug 2020 02:57:56

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:45', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f031ae03-edb2-44f7-aa79-7dc2835673b0' User entered 'No (N)'	System	12 Aug 2020 02:57:56
	System	12 Aug 2020 02:57:56

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:47', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f031ae03-edb2-44f7-aa79-7dc2835673b0' User entered 'No (N)'	System	12 Aug 2020 02:57:56
	System	12 Aug 2020 02:57:56

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:50', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f031ae03-edb2-44f7-aa79-7dc2835673b0' User entered 'None (1)'	System	12 Aug 2020 02:57:56
	System	12 Aug 2020 02:57:56

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:54', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f031ae03-edb2-44f7-aa79-7dc2835673b0'	System	12 Aug 2020 02:57:56
User entered '11 Aug 2020 22:57'	System	12 Aug 2020 02:57:56

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 4'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:08', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '2d7552dd-9fe0-474a-9e5f-e0cbd816d126' User entered 'None (1)'	System	13 Aug 2020 03:05:18
	System	13 Aug 2020 03:05:18

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:10', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '2d7552dd-9fe0-474a-9e5f-e0cbd816d126' User entered 'No (N)'	System	13 Aug 2020 03:05:18
	System	13 Aug 2020 03:05:18

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:11', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '2d7552dd-9fe0-474a-9e5f-e0cbd816d126' User entered 'No (N)'	System	13 Aug 2020 03:05:18
	System	13 Aug 2020 03:05:18

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:12', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '2d7552dd-9fe0-474a-9e5f-e0cbd816d126' User entered 'None (1)'	System	13 Aug 2020 03:05:18
	System	13 Aug 2020 03:05:18

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:15', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '2d7552dd-9fe0-474a-9e5f-e0cbd816d126' User entered '12 Aug 2020 23:05'	System	13 Aug 2020 03:05:18
	System	13 Aug 2020 03:05:18

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '12 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '13 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 5'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:04', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '8156b547-aa37-426a-b032-6b78eb941f3f' User entered 'None (1)'	System	14 Aug 2020 01:30:23
	System	14 Aug 2020 01:30:23

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:15', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '8156b547-aa37-426a-b032-6b78eb941f3f' User entered 'No (N)'	System	14 Aug 2020 01:30:23
	System	14 Aug 2020 01:30:23

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:17', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '8156b547-aa37-426a-b032-6b78eb941f3f' User entered 'No (N)'	System	14 Aug 2020 01:30:23
	System	14 Aug 2020 01:30:23

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:19', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '8156b547-aa37-426a-b032-6b78eb941f3f' User entered 'None (1)'	System	14 Aug 2020 01:30:23
	System	14 Aug 2020 01:30:23

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:21', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '8156b547-aa37-426a-b032-6b78eb941f3f' User entered '13 Aug 2020 21:30'	System	14 Aug 2020 01:30:23
	System	14 Aug 2020 01:30:23

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '13 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '14 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 6'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:35', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'cdb222b3-7a66-4b98-85ac-1c066ebf050c' User entered 'None (1)'	System	15 Aug 2020 13:35:44
	System	15 Aug 2020 13:35:44

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:37', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'cdb222b3-7a66-4b98-85ac-1c066ebf050c' User entered 'No (N)'	System	15 Aug 2020 13:35:44
	System	15 Aug 2020 13:35:44

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:38', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'cdb222b3-7a66-4b98-85ac-1c066ebf050c' User entered 'No (N)'	System	15 Aug 2020 13:35:44
	System	15 Aug 2020 13:35:44

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:39', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'cdb222b3-7a66-4b98-85ac-1c066ebf050c' User entered 'None (1)'	System	15 Aug 2020 13:35:44
	System	15 Aug 2020 13:35:44

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:41', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'cdb222b3-7a66-4b98-85ac-1c066ebf050c' User entered '15 Aug 2020 09:35'	System	15 Aug 2020 13:35:44
	System	15 Aug 2020 13:35:44

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '14 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '15 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 7'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:30:39', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '0ec1f899-44b3-49a6-b83a-9bf54dc0efbb'	System	16 Aug 2020 01:30:47
User entered 'None (1)'	System	16 Aug 2020 01:30:47

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:30:40', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '0ec1f899-44b3-49a6-b83a-9bf54dc0efbb' User entered 'No (N)'	System	16 Aug 2020 01:30:47
	System	16 Aug 2020 01:30:47

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:30:41', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '0ec1f899-44b3-49a6-b83a-9bf54dc0efbb' User entered 'No (N)'	System	16 Aug 2020 01:30:47
	System	16 Aug 2020 01:30:47

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:30:43', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '0ec1f899-44b3-49a6-b83a-9bf54dc0efbb'	System	16 Aug 2020 01:30:47
User entered 'None (1)'	System	16 Aug 2020 01:30:47

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:30:45', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '0ec1f899-44b3-49a6-b83a-9bf54dc0efbb' User entered '15 Aug 2020 21:30'	System	16 Aug 2020 01:30:47
	System	16 Aug 2020 01:30:47

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '15 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '16 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:35', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '46c310e0-f7d9-445d-b808-93ded1e707a8' User entered 'None (0)'	System	09 Aug 2020 17:42:53
	System	09 Aug 2020 17:42:53

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:37', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '46c310e0-f7d9-445d-b808-93ded1e707a8' User entered 'None (0)'	System	09 Aug 2020 17:42:53
	System	09 Aug 2020 17:42:53

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:39', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '46c310e0-f7d9-445d-b808-93ded1e707a8' User entered 'None (0)'	System	09 Aug 2020 17:42:53
	System	09 Aug 2020 17:42:53

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:41', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '46c310e0-f7d9-445d-b808-93ded1e707a8' User entered 'None (0)'	System	09 Aug 2020 17:42:53
	System	09 Aug 2020 17:42:53

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:42', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '46c310e0-f7d9-445d-b808-93ded1e707a8' User entered 'None (0)'	System	09 Aug 2020 17:42:53
	System	09 Aug 2020 17:42:53

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:44', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '46c310e0-f7d9-445d-b808-93ded1e707a8' User entered 'None (0)'	System	09 Aug 2020 17:42:53
	System	09 Aug 2020 17:42:53

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:48', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '46c310e0-f7d9-445d-b808-93ded1e707a8' User entered 'No (N)'	System	09 Aug 2020 17:42:53
	System	09 Aug 2020 17:42:53

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T13:42:51', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '46c310e0-f7d9-445d-b808-93ded1e707a8' User entered '09 Aug 2020 13:42'	System	09 Aug 2020 17:42:53
	System	09 Aug 2020 17:42:53

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '09 Aug 2020 13:25'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '09 Aug 2020 15:55'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 1, after vaccination (at home)'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:21:01', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '805e106d-61de-465a-849b-0f45382fae26' User entered 'None (0)'	System	10 Aug 2020 02:21:19
	System	10 Aug 2020 02:21:19

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:21:03', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '805e106d-61de-465a-849b-0f45382fae26' User entered 'None (0)'	System	10 Aug 2020 02:21:19
	System	10 Aug 2020 02:21:19

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:21:06', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '805e106d-61de-465a-849b-0f45382fae26' User entered 'None (0)'	System	10 Aug 2020 02:21:19
	System	10 Aug 2020 02:21:19

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:21:08', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '805e106d-61de-465a-849b-0f45382fae26' User entered 'None (0)'	System	10 Aug 2020 02:21:19
	System	10 Aug 2020 02:21:19

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:21:10', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '805e106d-61de-465a-849b-0f45382fae26' User entered 'None (0)'	System	10 Aug 2020 02:21:19
	System	10 Aug 2020 02:21:19

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:21:12', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '805e106d-61de-465a-849b-0f45382fae26' User entered 'None (0)'	System	10 Aug 2020 02:21:19
	System	10 Aug 2020 02:21:19

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:21:15', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '805e106d-61de-465a-849b-0f45382fae26' User entered 'No (N)'	System	10 Aug 2020 02:21:19
	System	10 Aug 2020 02:21:19

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-09T22:21:17', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '805e106d-61de-465a-849b-0f45382fae26' User entered '09 Aug 2020 22:21'	System	10 Aug 2020 02:21:19
	System	10 Aug 2020 02:21:19

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '09 Aug 2020 16:50'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '10 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 2'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:09:10', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '453a586b-a0fe-4012-b3f3-f0b8107f0393' User entered 'None (0)'	System	11 Aug 2020 02:09:30
	System	11 Aug 2020 02:09:30

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:09:13', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '453a586b-a0fe-4012-b3f3-f0b8107f0393' User entered 'None (0)'	System	11 Aug 2020 02:09:30
	System	11 Aug 2020 02:09:30

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:09:16', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '453a586b-a0fe-4012-b3f3-f0b8107f0393' User entered 'None (0)'	System	11 Aug 2020 02:09:30
	System	11 Aug 2020 02:09:30

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:09:19', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '453a586b-a0fe-4012-b3f3-f0b8107f0393' User entered 'None (0)'	System	11 Aug 2020 02:09:30
	System	11 Aug 2020 02:09:30

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:09:21', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '453a586b-a0fe-4012-b3f3-f0b8107f0393' User entered 'None (0)'	System	11 Aug 2020 02:09:30
	System	11 Aug 2020 02:09:30

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:09:23', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '453a586b-a0fe-4012-b3f3-f0b8107f0393' User entered 'None (0)'	System	11 Aug 2020 02:09:30
	System	11 Aug 2020 02:09:30

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:09:25', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '453a586b-a0fe-4012-b3f3-f0b8107f0393'	System	11 Aug 2020 02:09:30
User entered 'No (N)'	System	11 Aug 2020 02:09:30

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-10T22:09:28', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '453a586b-a0fe-4012-b3f3-f0b8107f0393' User entered '10 Aug 2020 22:09'	System	11 Aug 2020 02:09:30
	System	11 Aug 2020 02:09:30

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 3'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:21', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a6cfa2ff-2f18-438d-a36d-9c50a98606d1' User entered 'None (0)'	System	12 Aug 2020 02:57:40
	System	12 Aug 2020 02:57:40

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:23', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a6cfa2ff-2f18-438d-a36d-9c50a98606d1' User entered 'None (0)'	System	12 Aug 2020 02:57:40
	System	12 Aug 2020 02:57:40

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:24', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a6cfa2ff-2f18-438d-a36d-9c50a98606d1' User entered 'None (0)'	System	12 Aug 2020 02:57:40
	System	12 Aug 2020 02:57:40

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:26', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a6cfa2ff-2f18-438d-a36d-9c50a98606d1' User entered 'None (0)'	System	12 Aug 2020 02:57:40
	System	12 Aug 2020 02:57:40

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:28', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a6cfa2ff-2f18-438d-a36d-9c50a98606d1' User entered 'None (0)'	System	12 Aug 2020 02:57:40
	System	12 Aug 2020 02:57:40

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:29', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a6cfa2ff-2f18-438d-a36d-9c50a98606d1' User entered 'None (0)'	System	12 Aug 2020 02:57:40
	System	12 Aug 2020 02:57:40

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:35', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a6cfa2ff-2f18-438d-a36d-9c50a98606d1' User entered 'No (N)'	System	12 Aug 2020 02:57:40
	System	12 Aug 2020 02:57:40

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-11T22:57:38', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a6cfa2ff-2f18-438d-a36d-9c50a98606d1' User entered '11 Aug 2020 22:57'	System	12 Aug 2020 02:57:40
	System	12 Aug 2020 02:57:40

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 4'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:18', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd94aa61c-768d-47ee-bab3-ed1e361c084e' User entered 'None (0)'	System	13 Aug 2020 03:05:32
	System	13 Aug 2020 03:05:32

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:19', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd94aa61c-768d-47ee-bab3-ed1e361c084e' User entered 'None (0)'	System	13 Aug 2020 03:05:32
	System	13 Aug 2020 03:05:32

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:21', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd94aa61c-768d-47ee-bab3-ed1e361c084e' User entered 'None (0)'	System	13 Aug 2020 03:05:32
	System	13 Aug 2020 03:05:32

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:22', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd94aa61c-768d-47ee-bab3-ed1e361c084e' User entered 'None (0)'	System	13 Aug 2020 03:05:32
	System	13 Aug 2020 03:05:32

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:24', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd94aa61c-768d-47ee-bab3-ed1e361c084e' User entered 'None (0)'	System	13 Aug 2020 03:05:32
	System	13 Aug 2020 03:05:32

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:25', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd94aa61c-768d-47ee-bab3-ed1e361c084e' User entered 'None (0)'	System	13 Aug 2020 03:05:32
	System	13 Aug 2020 03:05:32

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:27', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd94aa61c-768d-47ee-bab3-ed1e361c084e' User entered 'No (N)'	System	13 Aug 2020 03:05:32
	System	13 Aug 2020 03:05:32

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-12T23:05:29', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd94aa61c-768d-47ee-bab3-ed1e361c084e' User entered '12 Aug 2020 23:05'	System	13 Aug 2020 03:05:32
	System	13 Aug 2020 03:05:32

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '12 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '13 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 5'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:25', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '29eb8264-c5da-4356-a712-2353148391ca' User entered 'None (0)'	System	14 Aug 2020 01:30:38
	System	14 Aug 2020 01:30:38

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:26', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '29eb8264-c5da-4356-a712-2353148391ca' User entered 'None (0)'	System	14 Aug 2020 01:30:38
	System	14 Aug 2020 01:30:38

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:28', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '29eb8264-c5da-4356-a712-2353148391ca' User entered 'None (0)'	System	14 Aug 2020 01:30:38
	System	14 Aug 2020 01:30:38

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:29', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '29eb8264-c5da-4356-a712-2353148391ca' User entered 'None (0)'	System	14 Aug 2020 01:30:38
	System	14 Aug 2020 01:30:38

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:31', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '29eb8264-c5da-4356-a712-2353148391ca' User entered 'None (0)'	System	14 Aug 2020 01:30:38
	System	14 Aug 2020 01:30:38

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:32', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '29eb8264-c5da-4356-a712-2353148391ca' User entered 'None (0)'	System	14 Aug 2020 01:30:38
	System	14 Aug 2020 01:30:38

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:33', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '29eb8264-c5da-4356-a712-2353148391ca' User entered 'No (N)'	System	14 Aug 2020 01:30:38
	System	14 Aug 2020 01:30:38

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-13T21:30:36', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '29eb8264-c5da-4356-a712-2353148391ca' User entered '13 Aug 2020 21:30'	System	14 Aug 2020 01:30:38
	System	14 Aug 2020 01:30:38

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '13 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '14 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 6'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:45', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'acdac17c-794e-4513-9799-1c153d051b12' User entered 'None (0)'	System	15 Aug 2020 13:35:57
	System	15 Aug 2020 13:35:57

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:46', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'acdac17c-794e-4513-9799-1c153d051b12' User entered 'None (0)'	System	15 Aug 2020 13:35:57
	System	15 Aug 2020 13:35:57

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:47', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'acdac17c-794e-4513-9799-1c153d051b12' User entered 'None (0)'	System	15 Aug 2020 13:35:57
	System	15 Aug 2020 13:35:57

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:49', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'acdac17c-794e-4513-9799-1c153d051b12' User entered 'None (0)'	System	15 Aug 2020 13:35:57
	System	15 Aug 2020 13:35:57

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:50', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'acdac17c-794e-4513-9799-1c153d051b12' User entered 'None (0)'	System	15 Aug 2020 13:35:57
	System	15 Aug 2020 13:35:57

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:51', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'acdac17c-794e-4513-9799-1c153d051b12' User entered 'None (0)'	System	15 Aug 2020 13:35:57
	System	15 Aug 2020 13:35:57

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:53', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'acdac17c-794e-4513-9799-1c153d051b12' User entered 'No (N)'	System	15 Aug 2020 13:35:57
	System	15 Aug 2020 13:35:57

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T09:35:55', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'acdac17c-794e-4513-9799-1c153d051b12' User entered '15 Aug 2020 09:35'	System	15 Aug 2020 13:35:57
	System	15 Aug 2020 13:35:57

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '14 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '15 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 7'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:30:49', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f6003f66-d975-43eb-b2cf-ca80b98a4f92' User entered 'None (0)'	System	16 Aug 2020 01:31:06
	System	16 Aug 2020 01:31:06

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:30:50', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f6003f66-d975-43eb-b2cf-ca80b98a4f92' User entered 'None (0)'	System	16 Aug 2020 01:31:06
	System	16 Aug 2020 01:31:06

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:30:51', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f6003f66-d975-43eb-b2cf-ca80b98a4f92' User entered 'None (0)'	System	16 Aug 2020 01:31:06
	System	16 Aug 2020 01:31:06

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:30:54', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f6003f66-d975-43eb-b2cf-ca80b98a4f92' User entered 'None (0)'	System	16 Aug 2020 01:31:06
	System	16 Aug 2020 01:31:06

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:30:59', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f6003f66-d975-43eb-b2cf-ca80b98a4f92' User entered 'None (0)'	System	16 Aug 2020 01:31:06
	System	16 Aug 2020 01:31:06

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:31:01', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f6003f66-d975-43eb-b2cf-ca80b98a4f92' User entered 'None (0)'	System	16 Aug 2020 01:31:06
	System	16 Aug 2020 01:31:06

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:31:02', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f6003f66-d975-43eb-b2cf-ca80b98a4f92'	System	16 Aug 2020 01:31:06
User entered 'No (N)'	System	16 Aug 2020 01:31:06

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-08-15T21:31:04', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f6003f66-d975-43eb-b2cf-ca80b98a4f92' User entered '15 Aug 2020 21:31'	System	16 Aug 2020 01:31:06
	System	16 Aug 2020 01:31:06

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '15 Aug 2020 12:00'	System	09 Aug 2020 17:39:08

US3402316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '16 Aug 2020 11:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	24 Aug 2020 22:20:42

US3402316

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '16 Aug 2020'	Traci Hull (b) (4)	24 Aug 2020 22:20:42

US3402316

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	24 Aug 2020 22:20:42

US3402316

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	Traci Hull (b) (4)	24 Aug 2020 22:20:42

US3402316

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Aug 2020 22:20:48

US3402316

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'I'	System	24 Aug 2020 22:20:48

US3402316

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	24 Aug 2020 22:21:03

US3402316

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered '23 Aug 2020'	Traci Hull (b) (4)	24 Aug 2020 22:21:03

US3402316

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	24 Aug 2020 22:21:03

US3402316

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered empty.	Traci Hull (b) (4)	24 Aug 2020 22:21:03

US3402316

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Aug 2020 22:21:10

US3402316

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'I'	System	24 Aug 2020 22:21:10

US3402316

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Yes (Y)'	Traci Hull (b) (4)	01 Sep 2020 11:46:21

US3402316

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered '31 Aug 2020'	Traci Hull (b) (4)	01 Sep 2020 11:46:21

US3402316

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	01 Sep 2020 11:46:21

US3402316

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered empty.	Traci Hull (b) (4)	01 Sep 2020 11:46:21

US3402316

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Yes (Y)'	Traci Hull (b) (4)	01 Sep 2020 11:46:24

US3402316

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'I'	System	01 Sep 2020 11:46:24

US3402316

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	11 Sep 2020 19:28:41

US3402316

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '11 Sep 2020'	Jennifer Molstead (b) (4)	11 Sep 2020 19:28:41

US3402316

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	11 Sep 2020 19:28:41

US3402316

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'VISIT2'	System	11 Sep 2020 19:28:41

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4) (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '11 Sep 2020'	Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '14:43'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered '11 Sep 2020 14:43'	System	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '98.5' F	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '90'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'bpm'	System	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '14'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'breaths/min'	System	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '111'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'mmHg'	System	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '73'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'mmHg'	System	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '11 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '15:53'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered '11 Sep 2020 15:53'	System	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '98.7' F	Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29
	(b) (4)	

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '71'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'bpm'	System	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '14'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'breaths/min'	System	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '106'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'mmHg'	System	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '74'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'mmHg'	System	11 Sep 2020 20:14:29

US3402316

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:14:39

US3402316

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '11 Sep 2020'	Tammy Kohn (b) (4)	11 Sep 2020 20:14:39

US3402316

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	11 Sep 2020 20:15:17

US3402316

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '11 Sep 2020'	Tammy Kohn (b) (4)	11 Sep 2020 20:15:17

US3402316

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Urine (URINE)'	Tammy Kohn (b) (4)	11 Sep 2020 20:15:17

US3402316

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Negative (NEGATIVE)'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:15:17

US3402316

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User closed query 'Per CDM, please provide response to current question, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 11:56:57
Query 'Per CDM, please provide response to current question, otherwise clarify.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	12 Oct 2020 11:28:24
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	12 Oct 2020 11:28:21
User opened query 'Per CDM, please provide response to current question, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 10:39:22
User entered empty.	Tammy Kohn (b) (4) (b) (4)	11 Sep 2020 20:15:17

US3402316

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:15:17

US3402316

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:15:17

US3402316

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:36:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered empty.	System	11 Sep 2020 20:15:17

US3402316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	11 Sep 2020 19:28:28

US3402316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	Jennifer Molstead (b) (4)	11 Sep 2020 19:28:28

US3402316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	Jennifer Molstead (b) (4)	11 Sep 2020 19:28:28

US3402316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 19:28:28

US3402316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '11 Sep 2020'	Jennifer Molstead (b) (4)	11 Sep 2020 19:28:28

US3402316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '15:19'	Jennifer Molstead (b) (4)	11 Sep 2020 19:28:28

US3402316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered '11 Sep 2020 15:19'	System	11 Sep 2020 19:28:28

US3402316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	11 Sep 2020 19:28:28

US3402316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'ONCE'	System	11 Sep 2020 19:28:28

US3402316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 19:28:28

US3402316

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	11 Sep 2020 20:15:54

US3402316

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '11 Sep 2020'	Tammy Kohn (b) (4)	11 Sep 2020 20:15:54

US3402316

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '15:04'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:15:54

US3402316

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered '11 Sep 2020 15:04'	System	11 Sep 2020 20:15:54

US3402316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:36:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '11 Sep 2020'	Tammy Kohn (b) (4)	11 Sep 2020 20:16:11

US3402316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tammy Kohn (b) (4) (b) (4)	11 Sep 2020 20:16:11

US3402316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:16:11

US3402316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '15:03'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:16:11

US3402316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered '11 Sep 2020 15:03'	System	11 Sep 2020 20:16:11

US3402316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tammy Kohn (b) (4) (b) (4)	11 Sep 2020 20:16:11

US3402316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:16:11

US3402316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:03

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:16:11

US3402316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered empty.	System	11 Sep 2020 20:16:11

US3402316

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	11 Sep 2020 20:16:15

US3402316

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'I'	System	11 Sep 2020 20:16:15

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:54:22', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '863a7182-9695-4df6-927d-d1018496048c' User entered 'Yes (Y)'	System	11 Sep 2020 19:54:36
	System	11 Sep 2020 19:54:36

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:54:26', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '863a7182-9695-4df6-927d-d1018496048c' User entered '98.7'	System	11 Sep 2020 19:54:36
	System	11 Sep 2020 19:54:36

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:54:30', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '863a7182-9695-4df6-927d-d1018496048c' User entered 'No (N)'	System	11 Sep 2020 19:54:36
	System	11 Sep 2020 19:54:36

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:54:33', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '863a7182-9695-4df6-927d-d1018496048c' User entered '11 Sep 2020 15:54'	System	11 Sep 2020 19:54:36
	System	11 Sep 2020 19:54:36

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Sep 2020 15:39'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Sep 2020 18:09'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:35:31', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '74aae8ea-f743-4a03-aea1-cd971de2d830' User entered 'Yes (Y)'	System	12 Sep 2020 01:36:03
	System	12 Sep 2020 01:36:03

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:35:35', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '74aae8ea-f743-4a03-aea1-cd971de2d830' User entered '97.3'	System	12 Sep 2020 01:36:03
	System	12 Sep 2020 01:36:03

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:35:40', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '74aae8ea-f743-4a03-aea1-cd971de2d830'	System	12 Sep 2020 01:36:03
User entered 'Yes (Y)'	System	12 Sep 2020 01:36:03

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'PATIENT TOOK ACETAMINOPHEN FOR MILD INJECTION SITE PAIN. ' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 15:01:23
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Tammy Kohn (b) (4)	13 Oct 2020 17:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:35:53', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '74aae8ea-f743-4a03-aea1-cd971de2d830'	(b) (4)	
User entered '1'	System	12 Sep 2020 01:36:03
	System	12 Sep 2020 01:36:03
	System	12 Sep 2020 01:36:03

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:35:53', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '74aae8ea-f743-4a03-aea1-cd971de2d830' User entered '0'	System	12 Sep 2020 01:36:03
	System	12 Sep 2020 01:36:03

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:35:59', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '74aae8ea-f743-4a03-aea1-cd971de2d830' User entered '11 Sep 2020 21:35'	System	12 Sep 2020 01:36:03
	System	12 Sep 2020 01:36:03

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Sep 2020 19:04'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 2'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:06:12', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a0f23906-0c42-41dd-9156-49278680d25a' User entered 'Yes (Y)'	System	13 Sep 2020 02:06:29
	System	13 Sep 2020 02:06:29

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:06:17', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a0f23906-0c42-41dd-9156-49278680d25a' User entered '98.1'	System	13 Sep 2020 02:06:29
	System	13 Sep 2020 02:06:29

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:06:21', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a0f23906-0c42-41dd-9156-49278680d25a' User entered 'No (N)'	System	13 Sep 2020 02:06:29
	System	13 Sep 2020 02:06:29

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:06:26', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a0f23906-0c42-41dd-9156-49278680d25a' User entered '12 Sep 2020 22:06'	System	13 Sep 2020 02:06:29
	System	13 Sep 2020 02:06:29

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 3'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:05:12', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '715491e9-5973-4597-a59f-4fb595b1baff' User entered 'Yes (Y)'	System	14 Sep 2020 02:05:38
	System	14 Sep 2020 02:05:38

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:05:30', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '715491e9-5973-4597-a59f-4fb595b1baff' User entered '97.8'	System	14 Sep 2020 02:05:38
	System	14 Sep 2020 02:05:38

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:05:32', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '715491e9-5973-4597-a59f-4fb595b1baff'	System	14 Sep 2020 02:05:38
User entered 'No (N)'	System	14 Sep 2020 02:05:38

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:05:35', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '715491e9-5973-4597-a59f-4fb595b1baff' User entered '13 Sep 2020 22:05'	System	14 Sep 2020 02:05:38
	System	14 Sep 2020 02:05:38

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 4'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:56:26', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f39ce787-0ad6-4f9a-a57d-9c8947f7d57c' User entered 'Yes (Y)'	System	15 Sep 2020 00:56:52
	System	15 Sep 2020 00:56:52

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:56:33', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f39ce787-0ad6-4f9a-a57d-9c8947f7d57c' User entered '97.6'	System	15 Sep 2020 00:56:52
	System	15 Sep 2020 00:56:52

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:56:38', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f39ce787-0ad6-4f9a-a57d-9c8947f7d57c'	System	15 Sep 2020 00:56:52
User entered 'No (N)'	System	15 Sep 2020 00:56:52

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:56:49', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f39ce787-0ad6-4f9a-a57d-9c8947f7d57c'	System	15 Sep 2020 00:56:52
User entered '14 Sep 2020 20:56'	System	15 Sep 2020 00:56:52

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 5'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:22', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '1f61080c-de1d-4bb7-87a2-c0a5ae0a5703' User entered 'Yes (Y)'	System	16 Sep 2020 09:50:36
	System	16 Sep 2020 09:50:36

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:26', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '1f61080c-de1d-4bb7-87a2-c0a5ae0a5703' User entered '97.6'	System	16 Sep 2020 09:50:36
	System	16 Sep 2020 09:50:36

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:29', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '1f61080c-de1d-4bb7-87a2-c0a5ae0a5703' User entered 'No (N)'	System	16 Sep 2020 09:50:36
	System	16 Sep 2020 09:50:36

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:32', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '1f61080c-de1d-4bb7-87a2-c0a5ae0a5703' User entered '16 Sep 2020 05:50'	System	16 Sep 2020 09:50:36
	System	16 Sep 2020 09:50:36

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 6'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:20', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '23e44cfd-f599-4587-9c62-9ea9ecea409e' User entered 'Yes (Y)'	System	17 Sep 2020 01:09:32
	System	17 Sep 2020 01:09:32

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:24', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '23e44cfd-f599-4587-9c62-9ea9ecea409e' User entered '98.1'	System	17 Sep 2020 01:09:32
	System	17 Sep 2020 01:09:32

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:26', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '23e44cfd-f599-4587-9c62-9ea9ecea409e' User entered 'No (N)'	System	17 Sep 2020 01:09:32
	System	17 Sep 2020 01:09:32

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:28', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '23e44cfd-f599-4587-9c62-9ea9ecea409e' User entered '16 Sep 2020 21:09'	System	17 Sep 2020 01:09:32
	System	17 Sep 2020 01:09:32

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 7'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:20', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'e5fc6745-3834-4031-8726-28502ea4f68e' User entered 'Yes (Y)'	System	18 Sep 2020 01:08:29
	System	18 Sep 2020 01:08:29

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:23', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'e5fc6745-3834-4031-8726-28502ea4f68e' User entered '97.1'	System	18 Sep 2020 01:08:29
	System	18 Sep 2020 01:08:29

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:25', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'e5fc6745-3834-4031-8726-28502ea4f68e' User entered 'No (N)'	System	18 Sep 2020 01:08:29
	System	18 Sep 2020 01:08:29

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:27', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'e5fc6745-3834-4031-8726-28502ea4f68e' User entered '17 Sep 2020 21:08'	System	18 Sep 2020 01:08:29
	System	18 Sep 2020 01:08:29

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:54:48', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '6a3cb3fd-57e8-471d-ae5f-d40c0db0f3b9'	System	11 Sep 2020 19:55:06
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 19:55:06

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:54:53', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '6a3cb3fd-57e8-471d-ae5f-d40c0db0f3b9' User entered 'No (N)'	System	11 Sep 2020 19:55:06
	System	11 Sep 2020 19:55:06

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:54:55', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '6a3cb3fd-57e8-471d-ae5f-d40c0db0f3b9' User entered 'No (N)'	System	11 Sep 2020 19:55:06
	System	11 Sep 2020 19:55:06

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:54:59', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '6a3cb3fd-57e8-471d-ae5f-d40c0db0f3b9'	System	11 Sep 2020 19:55:06
User entered 'None (1)'	System	11 Sep 2020 19:55:06

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:55:02', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '6a3cb3fd-57e8-471d-ae5f-d40c0db0f3b9' User entered '11 Sep 2020 15:55'	System	11 Sep 2020 19:55:06
	System	11 Sep 2020 19:55:06

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Sep 2020 15:39'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Sep 2020 18:09'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:37:06', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f27ea2b6-4f63-4779-a26d-cff69afc92df'	System	12 Sep 2020 01:37:39
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 01:37:39

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:37:11', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f27ea2b6-4f63-4779-a26d-cff69afc92df' User entered 'No (N)'	System	12 Sep 2020 01:37:39
	System	12 Sep 2020 01:37:39

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:37:28', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f27ea2b6-4f63-4779-a26d-cff69afc92df' User entered 'No (N)'	System	12 Sep 2020 01:37:39
	System	12 Sep 2020 01:37:39

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:37:32', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f27ea2b6-4f63-4779-a26d-cff69afc92df' User entered 'None (1)'	System	12 Sep 2020 01:37:39
	System	12 Sep 2020 01:37:39

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:37:35', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'f27ea2b6-4f63-4779-a26d-cff69afc92df' User entered '11 Sep 2020 21:37'	System	12 Sep 2020 01:37:39
	System	12 Sep 2020 01:37:39

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Sep 2020 19:04'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 2'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:07:22', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'b6ed9485-4918-4696-8343-9dcc4e7df1ed'	System	13 Sep 2020 02:08:00
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 02:08:00

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:07:25', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'b6ed9485-4918-4696-8343-9dcc4e7df1ed' User entered 'No (N)'	System	13 Sep 2020 02:08:00
	System	13 Sep 2020 02:08:00

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:07:54', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'b6ed9485-4918-4696-8343-9dcc4e7df1ed' User entered 'No (N)'	System	13 Sep 2020 02:08:00
	System	13 Sep 2020 02:08:00

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:07:56', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'b6ed9485-4918-4696-8343-9dcc4e7df1ed'	System	13 Sep 2020 02:08:00
User entered 'None (1)'	System	13 Sep 2020 02:08:00

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:07:58', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'b6ed9485-4918-4696-8343-9dcc4e7df1ed' User entered '12 Sep 2020 22:07'	System	13 Sep 2020 02:08:00
	System	13 Sep 2020 02:08:00

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 3'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:05:39', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9dde84c0-7277-43d8-ab74-df5a1b898c01' User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 02:05:55
	System	14 Sep 2020 02:05:55

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:05:41', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9dde84c0-7277-43d8-ab74-df5a1b898c01' User entered 'No (N)'	System	14 Sep 2020 02:05:55
	System	14 Sep 2020 02:05:55

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:05:46', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9dde84c0-7277-43d8-ab74-df5a1b898c01' User entered 'No (N)'	System	14 Sep 2020 02:05:55
	System	14 Sep 2020 02:05:55

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:05:49', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9dde84c0-7277-43d8-ab74-df5a1b898c01' User entered 'None (1)'	System	14 Sep 2020 02:05:55
	System	14 Sep 2020 02:05:55

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:05:53', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9dde84c0-7277-43d8-ab74-df5a1b898c01' User entered '13 Sep 2020 22:05'	System	14 Sep 2020 02:05:55
	System	14 Sep 2020 02:05:55

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 4'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:56:54', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '95fb9ced-a444-434d-a916-687a22b19f06'	System	15 Sep 2020 00:57:07
User entered 'None (1)'	System	15 Sep 2020 00:57:07

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:56:57', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '95fb9ced-a444-434d-a916-687a22b19f06' User entered 'No (N)'	System	15 Sep 2020 00:57:07
	System	15 Sep 2020 00:57:07

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:56:59', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '95fb9ced-a444-434d-a916-687a22b19f06' User entered 'No (N)'	System	15 Sep 2020 00:57:07
	System	15 Sep 2020 00:57:07

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:57:02', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '95fb9ced-a444-434d-a916-687a22b19f06'	System	15 Sep 2020 00:57:07
User entered 'None (1)'	System	15 Sep 2020 00:57:07

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:57:03', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '95fb9ced-a444-434d-a916-687a22b19f06'	System	15 Sep 2020 00:57:07
User entered '14 Sep 2020 20:57'	System	15 Sep 2020 00:57:07

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 5'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:35', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a57d793d-43d3-4f8e-8cfb-fd0399a7cf87' User entered 'None (1)'	System	16 Sep 2020 09:50:44
	System	16 Sep 2020 09:50:44

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:37', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a57d793d-43d3-4f8e-8cfb-fd0399a7cf87' User entered 'No (N)'	System	16 Sep 2020 09:50:44
	System	16 Sep 2020 09:50:44

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:38', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a57d793d-43d3-4f8e-8cfb-fd0399a7cf87' User entered 'No (N)'	System	16 Sep 2020 09:50:44
	System	16 Sep 2020 09:50:44

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:39', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a57d793d-43d3-4f8e-8cfb-fd0399a7cf87' User entered 'None (1)'	System	16 Sep 2020 09:50:44
	System	16 Sep 2020 09:50:44

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:42', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a57d793d-43d3-4f8e-8cfb-fd0399a7cf87' User entered '16 Sep 2020 05:50'	System	16 Sep 2020 09:50:44
	System	16 Sep 2020 09:50:44

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 6'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:31', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '987633c9-a36b-439f-ba16-e9a1def47e5d' User entered 'None (1)'	System	17 Sep 2020 01:09:43
	System	17 Sep 2020 01:09:43

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:33', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '987633c9-a36b-439f-ba16-e9a1def47e5d' User entered 'No (N)'	System	17 Sep 2020 01:09:43
	System	17 Sep 2020 01:09:43

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:34', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '987633c9-a36b-439f-ba16-e9a1def47e5d' User entered 'No (N)'	System	17 Sep 2020 01:09:43
	System	17 Sep 2020 01:09:43

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:35', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '987633c9-a36b-439f-ba16-e9a1def47e5d' User entered 'None (1)'	System	17 Sep 2020 01:09:43
	System	17 Sep 2020 01:09:43

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:37', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '987633c9-a36b-439f-ba16-e9a1def47e5d' User entered '16 Sep 2020 21:09'	System	17 Sep 2020 01:09:43
	System	17 Sep 2020 01:09:43

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 7'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:30', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'eb66a247-76b2-434b-8e94-60e871888647'	System	18 Sep 2020 01:08:38
User entered 'None (1)'	System	18 Sep 2020 01:08:38

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:31', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'eb66a247-76b2-434b-8e94-60e871888647' User entered 'No (N)'	System	18 Sep 2020 01:08:38
	System	18 Sep 2020 01:08:38

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:32', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'eb66a247-76b2-434b-8e94-60e871888647' User entered 'No (N)'	System	18 Sep 2020 01:08:38

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:34', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'eb66a247-76b2-434b-8e94-60e871888647'	System	18 Sep 2020 01:08:38
User entered 'None (1)'	System	18 Sep 2020 01:08:38

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:35', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'eb66a247-76b2-434b-8e94-60e871888647' User entered '17 Sep 2020 21:08'	System	18 Sep 2020 01:08:38
	System	18 Sep 2020 01:08:38

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:55:07', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '76daf8f7-150b-49e5-93a0-e345251f9f7b' User entered 'None (0)'	System	11 Sep 2020 19:55:34
	System	11 Sep 2020 19:55:34

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:55:10', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '76daf8f7-150b-49e5-93a0-e345251f9f7b' User entered 'None (0)'	System	11 Sep 2020 19:55:34
	System	11 Sep 2020 19:55:34

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:55:16', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '76daf8f7-150b-49e5-93a0-e345251f9f7b' User entered 'None (0)'	System	11 Sep 2020 19:55:34
	System	11 Sep 2020 19:55:34

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:55:18', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '76daf8f7-150b-49e5-93a0-e345251f9f7b' User entered 'None (0)'	System	11 Sep 2020 19:55:34
	System	11 Sep 2020 19:55:34

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:55:19', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '76daf8f7-150b-49e5-93a0-e345251f9f7b' User entered 'None (0)'	System	11 Sep 2020 19:55:34
	System	11 Sep 2020 19:55:34

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:55:20', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '76daf8f7-150b-49e5-93a0-e345251f9f7b' User entered 'None (0)'	System	11 Sep 2020 19:55:34
	System	11 Sep 2020 19:55:34

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:55:27', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '76daf8f7-150b-49e5-93a0-e345251f9f7b' User entered 'No (N)'	System	11 Sep 2020 19:55:34
	System	11 Sep 2020 19:55:34

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T15:55:29', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '76daf8f7-150b-49e5-93a0-e345251f9f7b' User entered '11 Sep 2020 15:55'	System	11 Sep 2020 19:55:34
	System	11 Sep 2020 19:55:34

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Sep 2020 15:39'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Sep 2020 18:09'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:36:54', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'fc480977-de66-467a-8e37-3f73faa66d76' User entered 'None (0)'	System	12 Sep 2020 01:37:04
	System	12 Sep 2020 01:37:04

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:36:30', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'fc480977-de66-467a-8e37-3f73faa66d76'	System	12 Sep 2020 01:37:04
User entered 'No interference with activity (1)'	System	12 Sep 2020 01:37:04

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:36:38', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'fc480977-de66-467a-8e37-3f73faa66d76' User entered 'None (0)'	System	12 Sep 2020 01:37:04
	System	12 Sep 2020 01:37:04

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:36:37', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'fc480977-de66-467a-8e37-3f73faa66d76' User entered 'None (0)'	System	12 Sep 2020 01:37:04
	System	12 Sep 2020 01:37:04

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:36:36', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'fc480977-de66-467a-8e37-3f73faa66d76' User entered 'None (0)'	System	12 Sep 2020 01:37:04
	System	12 Sep 2020 01:37:04

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:36:41', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'fc480977-de66-467a-8e37-3f73faa66d76' User entered 'None (0)'	System	12 Sep 2020 01:37:04
	System	12 Sep 2020 01:37:04

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:36:48', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'fc480977-de66-467a-8e37-3f73faa66d76' User entered 'No (N)'	System	12 Sep 2020 01:37:04
	System	12 Sep 2020 01:37:04

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-11T21:36:58', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'fc480977-de66-467a-8e37-3f73faa66d76'	System	12 Sep 2020 01:37:04
User entered '11 Sep 2020 21:36'	System	12 Sep 2020 01:37:04

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '11 Sep 2020 19:04'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 2'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:06:30', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a8ae6da8-6bc5-4a31-a3a8-49a84531a046' User entered 'None (0)'	System	13 Sep 2020 02:06:54
	System	13 Sep 2020 02:06:54

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:06:37', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a8ae6da8-6bc5-4a31-a3a8-49a84531a046' User entered 'None (0)'	System	13 Sep 2020 02:06:54
	System	13 Sep 2020 02:06:54

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:06:40', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a8ae6da8-6bc5-4a31-a3a8-49a84531a046' User entered 'None (0)'	System	13 Sep 2020 02:06:54
	System	13 Sep 2020 02:06:54

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:06:42', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a8ae6da8-6bc5-4a31-a3a8-49a84531a046' User entered 'None (0)'	System	13 Sep 2020 02:06:54
	System	13 Sep 2020 02:06:54

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:06:44', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a8ae6da8-6bc5-4a31-a3a8-49a84531a046' User entered 'None (0)'	System	13 Sep 2020 02:06:54
	System	13 Sep 2020 02:06:54

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:06:46', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a8ae6da8-6bc5-4a31-a3a8-49a84531a046' User entered 'None (0)'	System	13 Sep 2020 02:06:54
	System	13 Sep 2020 02:06:54

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:06:50', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a8ae6da8-6bc5-4a31-a3a8-49a84531a046' User entered 'No (N)'	System	13 Sep 2020 02:06:54
	System	13 Sep 2020 02:06:54

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-12T22:06:52', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a8ae6da8-6bc5-4a31-a3a8-49a84531a046' User entered '12 Sep 2020 22:06'	System	13 Sep 2020 02:06:54
	System	13 Sep 2020 02:06:54

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 3'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:05:56', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a0de90e8-679e-4ee6-9fe4-f0de6461d87c' User entered 'None (0)'	System	14 Sep 2020 02:06:13
	System	14 Sep 2020 02:06:13

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:05:58', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a0de90e8-679e-4ee6-9fe4-f0de6461d87c' User entered 'None (0)'	System	14 Sep 2020 02:06:13
	System	14 Sep 2020 02:06:13

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:06:01', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a0de90e8-679e-4ee6-9fe4-f0de6461d87c' User entered 'None (0)'	System	14 Sep 2020 02:06:13
	System	14 Sep 2020 02:06:13

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:06:03', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a0de90e8-679e-4ee6-9fe4-f0de6461d87c' User entered 'None (0)'	System	14 Sep 2020 02:06:13
	System	14 Sep 2020 02:06:13

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:06:05', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a0de90e8-679e-4ee6-9fe4-f0de6461d87c' User entered 'None (0)'	System	14 Sep 2020 02:06:13
	System	14 Sep 2020 02:06:13

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:06:07', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a0de90e8-679e-4ee6-9fe4-f0de6461d87c' User entered 'None (0)'	System	14 Sep 2020 02:06:13
	System	14 Sep 2020 02:06:13

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:06:09', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a0de90e8-679e-4ee6-9fe4-f0de6461d87c' User entered 'No (N)'	System	14 Sep 2020 02:06:13

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-13T22:06:12', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a0de90e8-679e-4ee6-9fe4-f0de6461d87c' User entered '13 Sep 2020 22:06'	System	14 Sep 2020 02:06:13
	System	14 Sep 2020 02:06:13

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 4'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:57:07', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7049013a-db75-4254-ac90-411102b47f5a' User entered 'None (0)'	System	15 Sep 2020 00:57:26
	System	15 Sep 2020 00:57:26

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:57:11', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7049013a-db75-4254-ac90-411102b47f5a' User entered 'None (0)'	System	15 Sep 2020 00:57:26
	System	15 Sep 2020 00:57:26

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:57:13', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7049013a-db75-4254-ac90-411102b47f5a' User entered 'None (0)'	System	15 Sep 2020 00:57:26
	System	15 Sep 2020 00:57:26

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:57:15', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7049013a-db75-4254-ac90-411102b47f5a' User entered 'None (0)'	System	15 Sep 2020 00:57:26
	System	15 Sep 2020 00:57:26

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:57:17', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7049013a-db75-4254-ac90-411102b47f5a' User entered 'None (0)'	System	15 Sep 2020 00:57:26
	System	15 Sep 2020 00:57:26

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:57:19', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7049013a-db75-4254-ac90-411102b47f5a' User entered 'None (0)'	System	15 Sep 2020 00:57:26
	System	15 Sep 2020 00:57:26

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:57:22', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7049013a-db75-4254-ac90-411102b47f5a' User entered 'No (N)'	System	15 Sep 2020 00:57:26
	System	15 Sep 2020 00:57:26

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-14T20:57:24', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7049013a-db75-4254-ac90-411102b47f5a' User entered '14 Sep 2020 20:57'	System	15 Sep 2020 00:57:26
	System	15 Sep 2020 00:57:26

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 5'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:45', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '54b40509-750e-46a6-aed5-a993c14df152' User entered 'None (0)'	System	16 Sep 2020 09:51:00
	System	16 Sep 2020 09:51:00

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:46', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '54b40509-750e-46a6-aed5-a993c14df152' User entered 'None (0)'	System	16 Sep 2020 09:51:00
	System	16 Sep 2020 09:51:00

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:48', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '54b40509-750e-46a6-aed5-a993c14df152' User entered 'None (0)'	System	16 Sep 2020 09:51:00
	System	16 Sep 2020 09:51:00

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:49', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '54b40509-750e-46a6-aed5-a993c14df152' User entered 'None (0)'	System	16 Sep 2020 09:51:00
	System	16 Sep 2020 09:51:00

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:51', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '54b40509-750e-46a6-aed5-a993c14df152' User entered 'None (0)'	System	16 Sep 2020 09:51:00
	System	16 Sep 2020 09:51:00

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:52', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '54b40509-750e-46a6-aed5-a993c14df152' User entered 'None (0)'	System	16 Sep 2020 09:51:00
	System	16 Sep 2020 09:51:00

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:54', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '54b40509-750e-46a6-aed5-a993c14df152' User entered 'No (N)'	System	16 Sep 2020 09:51:00
	System	16 Sep 2020 09:51:00

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T05:50:56', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '54b40509-750e-46a6-aed5-a993c14df152'	System	16 Sep 2020 09:51:00
User entered '16 Sep 2020 05:50'	System	16 Sep 2020 09:51:00

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 6'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:40', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a70f74e8-ace8-4c4a-912f-c74e201cc5ee' User entered 'None (0)'	System	17 Sep 2020 01:09:57
	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:42', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a70f74e8-ace8-4c4a-912f-c74e201cc5ee'	System	17 Sep 2020 01:09:57
User entered 'No interference with activity (1)'	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:44', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a70f74e8-ace8-4c4a-912f-c74e201cc5ee' User entered 'None (0)'	System	17 Sep 2020 01:09:57
	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:45', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a70f74e8-ace8-4c4a-912f-c74e201cc5ee' User entered 'None (0)'	System	17 Sep 2020 01:09:57
	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:48', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a70f74e8-ace8-4c4a-912f-c74e201cc5ee' User entered 'None (0)'	System	17 Sep 2020 01:09:57
	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:50', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a70f74e8-ace8-4c4a-912f-c74e201cc5ee' User entered 'None (0)'	System	17 Sep 2020 01:09:57
	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:52', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a70f74e8-ace8-4c4a-912f-c74e201cc5ee' User entered 'No (N)'	System	17 Sep 2020 01:09:57
	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-16T21:09:54', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a70f74e8-ace8-4c4a-912f-c74e201cc5ee' User entered '16 Sep 2020 21:09'	System	17 Sep 2020 01:09:57
	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	11 Sep 2020 19:28:28
User entered 'Day 7'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:38', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '701b7c65-21aa-4336-87d2-000e1ca751f0' User entered 'None (0)'	System	18 Sep 2020 01:08:57
	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:42', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '701b7c65-21aa-4336-87d2-000e1ca751f0'	System	18 Sep 2020 01:08:57
User entered 'No interference with activity (1)'	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:43', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '701b7c65-21aa-4336-87d2-000e1ca751f0' User entered 'None (0)'	System	18 Sep 2020 01:08:57
	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:45', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '701b7c65-21aa-4336-87d2-000e1ca751f0' User entered 'None (0)'	System	18 Sep 2020 01:08:57
	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:46', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '701b7c65-21aa-4336-87d2-000e1ca751f0' User entered 'None (0)'	System	18 Sep 2020 01:08:57
	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:48', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '701b7c65-21aa-4336-87d2-000e1ca751f0' User entered 'None (0)'	System	18 Sep 2020 01:08:57
	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:52', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '701b7c65-21aa-4336-87d2-000e1ca751f0' User entered 'No (N)'	System	18 Sep 2020 01:08:57
	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-17T21:08:54', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '701b7c65-21aa-4336-87d2-000e1ca751f0' User entered '17 Sep 2020 21:08'	System	18 Sep 2020 01:08:57
	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 19:28:28

US3402316

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	17 Sep 2020 01:09:57
User entered 'Day 8'	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-18T22:27:45', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'b19adfdf-fa5f-43a9-a588-b3944601721e'	System	19 Sep 2020 02:30:37
User entered 'No interference with activity (1)'	System	19 Sep 2020 02:30:37

US3402316

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-18T22:27:49', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'b19adfdf-fa5f-43a9-a588-b3944601721e' User entered '18 Sep 2020 22:27'	System	19 Sep 2020 02:30:37
	System	19 Sep 2020 02:30:37

US3402316

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	18 Sep 2020 01:08:57
User entered 'Day 9'	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-20T09:37:48', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '2ec5f5b9-2aac-4471-89c4-2451387fecc0' User entered 'None (0)'	System	20 Sep 2020 13:37:53
	System	20 Sep 2020 13:37:53

US3402316

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:36:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-20T09:37:50', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '2ec5f5b9-2aac-4471-89c4-2451387fecc0' User entered '20 Sep 2020 09:37'	System	20 Sep 2020 13:37:53
	System	20 Sep 2020 13:37:53

US3402316

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	17 Sep 2020 01:09:57
User entered 'Day 8'	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-18T22:28:06', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '05fb62e3-8cfb-4576-9d49-49089157a04a' User entered 'No (N)'	System	19 Sep 2020 02:34:16
	System	19 Sep 2020 02:34:16

US3402316

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-18T22:28:09', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '05fb62e3-8cfb-4576-9d49-49089157a04a' User entered '18 Sep 2020 22:28'	System	19 Sep 2020 02:34:16
	System	19 Sep 2020 02:34:16

US3402316

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 01:09:57

US3402316

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	18 Sep 2020 01:08:57
User entered 'Day 9'	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-20T09:37:53', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '24726b42-68bd-4a5b-8331-21a4ea8b429a' User entered 'No (N)'	System	20 Sep 2020 13:37:59
	System	20 Sep 2020 13:37:59

US3402316

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:36:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-09-20T09:37:55', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '24726b42-68bd-4a5b-8331-21a4ea8b429a' User entered '20 Sep 2020 09:37'	System	20 Sep 2020 13:37:59
	System	20 Sep 2020 13:37:59

US3402316

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:36:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 01:08:57

US3402316

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:36:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 01:08:57

US3402316

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	18 Sep 2020 17:02:11

US3402316

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered '18 Sep 2020'	Tammy Kohn (b) (4)	18 Sep 2020 17:02:11

US3402316

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	18 Sep 2020 17:02:11

US3402316

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered empty.	Tammy Kohn (b) (4)	18 Sep 2020 17:02:11

US3402316

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	18 Sep 2020 17:02:18

US3402316

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'I'	System	18 Sep 2020 17:02:18

US3402316

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Yes (Y)'	Traci Hull (b) (4)	25 Sep 2020 18:21:43

US3402316

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	25 Sep 2020 18:23:03
answered by data change (Site from System).		
User entered '25 Sep 2020' reason for change: New Information	System	25 Sep 2020 18:23:03
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Traci Hull (b) (4)	25 Sep 2020 18:21:43
User entered '18 Sep 2020'	(b) (4)	
	System	25 Sep 2020 18:21:43
	Traci Hull (b) (4)	25 Sep 2020 18:21:43
	(b) (4)	

US3402316

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	25 Sep 2020 18:21:43

US3402316

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered empty.	Traci Hull (b) (4)	25 Sep 2020 18:21:43

US3402316

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Yes (Y)'	Traci Hull (b) (4)	25 Sep 2020 18:23:07

US3402316

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'I'	System	25 Sep 2020 18:23:07

US3402316

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)'	Traci Hull (b) (4)	05 Oct 2020 21:00:05

US3402316

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered '02 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 14:38:58
User entered '2 Oct 2020'	Traci Hull (b) (4)	05 Oct 2020 21:00:05

US3402316

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	05 Oct 2020 21:00:05

US3402316

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	Traci Hull (b) (4)	05 Oct 2020 21:00:05

US3402316

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:34
User entered 'Yes (Y)'	Traci Hull (b) (4)	05 Oct 2020 20:59:54

US3402316

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'I'	System	05 Oct 2020 20:59:54

US3402316

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	07 Dec 2020 20:33:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Nov 2020 11:32:04
Query 'Data is required. Please complete.' answered with 'DATA ENTERED IN ERROR' (Site from System).	Tammy Kohn (b) (4)	11 Nov 2020 16:56:19
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:55:53
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	11 Nov 2020 16:55:53
User entered 'No (N)'	Tammy Kohn (b) (4)	11 Nov 2020 16:55:09

US3402316

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Tammy Kohn (b) (4)	11 Nov 2020 16:55:09

US3402316

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered empty.	(b) (4) Tammy Kohn (b) (4)	11 Nov 2020 16:55:09

US3402316

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'VISIT3'	System	07 Dec 2020 20:33:39
User entered empty.	System	11 Nov 2020 16:55:53
User entered 'VISIT3'	System	11 Nov 2020 16:55:09

US3402316

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:54:56
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	07 Dec 2020 20:32:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Nov 2020 11:32:25
Query 'Data is required. Please complete.' answered with 'DATA ENTERED IN ERROR' (Site from System).	Tammy Kohn (b) (4)	11 Nov 2020 16:56:34
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 16:56:25
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	11 Nov 2020 16:56:25
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	11 Nov 2020 16:55:17

US3402316

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered '1'	System	07 Dec 2020 20:32:06
User entered empty.	System	11 Nov 2020 16:56:25
User entered '1'	System	11 Nov 2020 16:55:17

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 64'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-09T05:13:37', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '19933a32-14c2-434b-bb38-081114867768'	System	09 Oct 2020 09:14:20
User entered 'No (N)'	System	09 Oct 2020 09:14:20

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Have you been exposed to someone with 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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-09T05:13:42', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '19933a32-14c2-434b-bb38-081114867768'	System	09 Oct 2020 09:14:20
User entered 'Yes (Y)'	System	09 Oct 2020 09:14:20

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Please 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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-09T05:13:50', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '19933a32-14c2-434b-bb38-081114867768'	System	09 Oct 2020 09:14:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Oct 2020 09:14:20

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-09T05:14:11', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '19933a32-14c2-434b-bb38-081114867768' User entered '09 Oct 2020 05:14:11'	System	09 Oct 2020 09:14:20
	System	09 Oct 2020 09:14:20

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered '09 Oct 2020 00:01'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered '13 Oct 2020 23:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 71'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-16T00:01:20', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '204d0e22-1cd7-4478-9e70-c1277ec5de6e' User entered 'Yes (Y)'	System	16 Oct 2020 04:01:52
	System	16 Oct 2020 04:01:52

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-16T00:01:35', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '204d0e22-1cd7-4478-9e70-c1277ec5de6e'	System	16 Oct 2020 04:01:52
User entered 'No (N)'	System	16 Oct 2020 04:01:52

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-16T00:01:42', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '204d0e22-1cd7-4478-9e70-c1277ec5de6e' User entered 'No (N)'	System	16 Oct 2020 04:01:52
	System	16 Oct 2020 04:01:52

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-16T00:01:48', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '204d0e22-1cd7-4478-9e70-c1277ec5de6e' User entered 'No (N)'	System	16 Oct 2020 04:01:52
	System	16 Oct 2020 04:01:52

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-16T00:01:50', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '204d0e22-1cd7-4478-9e70-c1277ec5de6e' User entered '16 Oct 2020 00:01:50'	System	16 Oct 2020 04:01:52
	System	16 Oct 2020 04:01:52

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered '16 Oct 2020 00:01'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered '20 Oct 2020 23:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 78'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-23T07:09:11', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd1eef42a-0175-4854-a50e-ddddd48dc749'	System	23 Oct 2020 11:09:35
User entered 'No (N)'	System	23 Oct 2020 11:09:35

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-23T07:09:19', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd1eef42a-0175-4854-a50e-ddddd48dc749'	System	23 Oct 2020 11:09:35
User entered 'Yes (Y)'	System	23 Oct 2020 11:09:35

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Please 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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-23T07:09:22', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd1eef42a-0175-4854-a50e-ddddd48dc749'	System	23 Oct 2020 11:09:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Oct 2020 11:09:35

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-10-23T07:09:25', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd1eef42a-0175-4854-a50e-ddddd48dc749' User entered '23 Oct 2020 07:09:25'	System	23 Oct 2020 11:09:35
	System	23 Oct 2020 11:09:35

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered '23 Oct 2020 00:01'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered '27 Oct 2020 23:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 92'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-11-10T11:59:10', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd6037e8b-b391-44e2-8483-f179887bee18' User entered 'No (N)'	System	10 Nov 2020 16:59:19
	System	10 Nov 2020 16:59:19

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-11-10T11:59:11', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd6037e8b-b391-44e2-8483-f179887bee18' User entered 'No (N)'	System	10 Nov 2020 16:59:19
	System	10 Nov 2020 16:59:19

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-11-10T11:59:14', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd6037e8b-b391-44e2-8483-f179887bee18' User entered '10 Nov 2020 11:59:14'	System	10 Nov 2020 16:59:19
	System	10 Nov 2020 16:59:19

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered '06 Nov 2020 00:01'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered '10 Nov 2020 23:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered 'Day 99'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-11-14T08:13:43', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'be0610b1-0743-4879-b3f9-bd5f9c5f357a' User entered 'No (N)'	System	14 Nov 2020 13:13:48
	System	14 Nov 2020 13:13:48

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-11-14T08:13:44', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'be0610b1-0743-4879-b3f9-bd5f9c5f357a' User entered 'No (N)'	System	14 Nov 2020 13:13:48
	System	14 Nov 2020 13:13:48

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-11-14T08:13:46', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'be0610b1-0743-4879-b3f9-bd5f9c5f357a' User entered '14 Nov 2020 08:13:46'	System	14 Nov 2020 13:13:48
	System	14 Nov 2020 13:13:48

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered '13 Nov 2020 00:01'	System	09 Aug 2020 17:39:08

US3402316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:25:06
Data entry locked.	System	09 Aug 2020 17:39:08
User entered '17 Nov 2020 23:59'	System	09 Aug 2020 17:39:08

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-12-03T12:36:48', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'afbdf32f-ab5c-4783-aa80-7692f63788a8' User entered 'No (N)'	System	03 Dec 2020 17:36:58
	System	03 Dec 2020 17:36:58

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-12-03T12:36:49', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'afbdf32f-ab5c-4783-aa80-7692f63788a8' User entered 'No (N)'	System	03 Dec 2020 17:36:58

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-12-03T12:36:51', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'afbdf32f-ab5c-4783-aa80-7692f63788a8' User entered '03 Dec 2020 12:36:51'	System	03 Dec 2020 17:36:58
	System	03 Dec 2020 17:36:58

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-12-08T05:55:01', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7cf063b3-a557-4aa1-ab3f-1ab885813b01'	System	08 Dec 2020 10:55:08
User entered 'No (N)'	System	08 Dec 2020 10:55:08

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-12-08T05:55:03', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7cf063b3-a557-4aa1-ab3f-1ab885813b01'	System	08 Dec 2020 10:55:08
User entered 'No (N)'	System	08 Dec 2020 10:55:08

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-12-08T05:55:05', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7cf063b3-a557-4aa1-ab3f-1ab885813b01' User entered '08 Dec 2020 05:55:05'	System	08 Dec 2020 10:55:08
	System	08 Dec 2020 10:55:08

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-12-17T12:00:33', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '4a15405d-c734-469b-af60-17201124c50c' User entered 'No (N)'	System	17 Dec 2020 17:00:43
	System	17 Dec 2020 17:00:43

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-12-17T12:00:36', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '4a15405d-c734-469b-af60-17201124c50c' User entered 'No (N)'	System	17 Dec 2020 17:00:43
	System	17 Dec 2020 17:00:43

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-12-17T12:00:39', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '4a15405d-c734-469b-af60-17201124c50c' User entered '17 Dec 2020 12:00:39'	System	17 Dec 2020 17:00:43
	System	17 Dec 2020 17:00:43

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-12-25T18:20:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '1a7c0197-b62a-45cc-b303-ccab74884467' User entered 'No (N)'	System	25 Dec 2020 23:20:07
	System	25 Dec 2020 23:20:07

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-12-25T18:20:01', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '1a7c0197-b62a-45cc-b303-ccab74884467'	System	25 Dec 2020 23:20:07
User entered 'No (N)'	System	25 Dec 2020 23:20:07

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2020-12-25T18:20:04', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '1a7c0197-b62a-45cc-b303-ccab74884467' User entered '25 Dec 2020 18:20:04'	System	25 Dec 2020 23:20:07
	System	25 Dec 2020 23:20:07

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-01-08T19:22:36', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9ca7f8a6-304f-452e-af1b-931f985a0816' User entered 'No (N)'	System	09 Jan 2021 00:22:42

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-01-08T19:22:37', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9ca7f8a6-304f-452e-af1b-931f985a0816'	System	09 Jan 2021 00:22:42
User entered 'No (N)'	System	09 Jan 2021 00:22:42

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-01-08T19:22:40', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '9ca7f8a6-304f-452e-af1b-931f985a0816' User entered '08 Jan 2021 19:22:40'	System	09 Jan 2021 00:22:42
	System	09 Jan 2021 00:22:42

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-01-14T12:00:22', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '27a23020-3016-4f87-8024-d4dc6de6c2ed' User entered 'No (N)'	System	04 Feb 2021 17:00:21
	System	04 Feb 2021 17:00:21

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-01-14T12:00:24', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '27a23020-3016-4f87-8024-d4dc6de6c2ed' User entered 'No (N)'	System	04 Feb 2021 17:00:21
	System	04 Feb 2021 17:00:21

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-01-14T12:00:27', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '27a23020-3016-4f87-8024-d4dc6de6c2ed' User entered '14 Jan 2021 12:00:27'	System	04 Feb 2021 17:00:21
	System	04 Feb 2021 17:00:21

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-02-04T12:00:10', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'ba6f81f4-3306-4b0d-98b7-9e92017b1b1f' User entered 'No (N)'	System	13 Feb 2021 16:59:14
	System	13 Feb 2021 16:59:14

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-02-04T12:00:12', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'ba6f81f4-3306-4b0d-98b7-9e92017b1b1f' User entered 'No (N)'	System	13 Feb 2021 16:59:14

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-02-04T12:00:14', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'ba6f81f4-3306-4b0d-98b7-9e92017b1b1f' User entered '04 Feb 2021 12:00:14'	System	13 Feb 2021 16:59:14

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-02-13T11:59:16', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '859fcb69-0c0d-45fb-925e-25ad263a864d' User entered 'No (N)'	System	13 Feb 2021 16:59:22

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-02-13T11:59:17', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '859fcb69-0c0d-45fb-925e-25ad263a864d'	System	13 Feb 2021 16:59:22
User entered 'No (N)'	System	13 Feb 2021 16:59:22

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-02-13T11:59:19', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '859fcb69-0c0d-45fb-925e-25ad263a864d' User entered '13 Feb 2021 11:59:19'	System	13 Feb 2021 16:59:22
	System	13 Feb 2021 16:59:22

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-02-19T17:59:34', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7640ac78-f165-4b9b-a553-b44c5463dba0' User entered 'No (N)'	System	19 Feb 2021 22:59:42

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-02-19T17:59:36', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7640ac78-f165-4b9b-a553-b44c5463dba0' User entered 'No (N)'	System	19 Feb 2021 22:59:42

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-02-19T17:59:38', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '7640ac78-f165-4b9b-a553-b44c5463dba0' User entered '19 Feb 2021 17:59:38'	System	19 Feb 2021 22:59:42
	System	19 Feb 2021 22:59:42

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-02-25T12:34:43-05:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '995c8761-7b95-4899-9ac4-0b326293fc95'	System	25 Feb 2021 17:34:50
User entered 'No (N)'	System	25 Feb 2021 17:34:50

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-02-25T12:34:44-05:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '995c8761-7b95-4899-9ac4-0b326293fc95'	System	25 Feb 2021 17:34:50
User entered 'No (N)'	System	25 Feb 2021 17:34:50

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-02-25T12:34:47-05:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '995c8761-7b95-4899-9ac4-0b326293fc95'	System	25 Feb 2021 17:34:50
User entered '25 Feb 2021 17:34:47'	System	25 Feb 2021 17:34:50

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-03-04T12:00:47-05:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '17c25e21-4338-47e9-b9c2-3c5dea80807c'	System	04 Mar 2021 17:02:18
User entered 'No (N)'	System	04 Mar 2021 17:02:18

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-03-04T12:00:48-05:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '17c25e21-4338-47e9-b9c2-3c5dea80807c'	System	04 Mar 2021 17:02:18
User entered 'No (N)'	System	04 Mar 2021 17:02:18

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-03-04T12:00:50-05:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '17c25e21-4338-47e9-b9c2-3c5dea80807c' User entered '04 Mar 2021 12:00:50'	System	04 Mar 2021 17:02:18
	System	04 Mar 2021 17:02:18

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-03-13T12:09:13-05:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '8a8199bf-b0b6-49e3-b880-daf06ada98f7'	System	13 Mar 2021 17:10:17
User entered 'No (N)'	System	13 Mar 2021 17:10:17

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-03-13T12:09:15-05:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '8a8199bf-b0b6-49e3-b880-daf06ada98f7'	System	13 Mar 2021 17:10:17
User entered 'No (N)'	System	13 Mar 2021 17:10:17

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-03-13T12:09:17-05:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '8a8199bf-b0b6-49e3-b880-daf06ada98f7'	System	13 Mar 2021 17:10:17
User entered '13 Mar 2021 12:09:17'	System	13 Mar 2021 17:10:17

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-03-25T12:00:19-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd27bb73d-346f-49ad-a139-4f07f55d05cc'	System	25 Mar 2021 16:00:38
User entered 'No (N)'	System	25 Mar 2021 16:00:38

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-03-25T12:00:20-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd27bb73d-346f-49ad-a139-4f07f55d05cc'	System	25 Mar 2021 16:00:38
User entered 'No (N)'	System	25 Mar 2021 16:00:38

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-03-25T12:00:22-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'd27bb73d-346f-49ad-a139-4f07f55d05cc' User entered '25 Mar 2021 12:00:22'	System	25 Mar 2021 16:00:38
	System	25 Mar 2021 16:00:38

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-04-01T13:07:44-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '92eb3902-f906-497c-8cca-40f69890195a' User entered 'No (N)'	System	01 Apr 2021 17:08:40
	System	01 Apr 2021 17:08:40

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-04-01T13:07:45-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '92eb3902-f906-497c-8cca-40f69890195a' User entered 'No (N)'	System	01 Apr 2021 17:08:40
	System	01 Apr 2021 17:08:40

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-04-01T13:07:48-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '92eb3902-f906-497c-8cca-40f69890195a' User entered '01 Apr 2021 13:07:48'	System	01 Apr 2021 17:08:40
	System	01 Apr 2021 17:08:40

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-04-15T12:17:11-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '31a7307c-a44c-4e37-9a8f-5c576302751c' User entered 'No (N)'	System	15 Apr 2021 16:19:35
	System	15 Apr 2021 16:19:35

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-04-15T12:17:12-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '31a7307c-a44c-4e37-9a8f-5c576302751c' User entered 'No (N)'	System	15 Apr 2021 16:19:35
	System	15 Apr 2021 16:19:35

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-04-15T12:17:14-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '31a7307c-a44c-4e37-9a8f-5c576302751c' User entered '15 Apr 2021 12:17:14'	System	15 Apr 2021 16:19:35
	System	15 Apr 2021 16:19:35

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-04-23T18:11:41-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '17ea209d-ff26-4ff3-8dfc-53375d88057a' User entered 'No (N)'	System	29 Apr 2021 16:19:38
	System	29 Apr 2021 16:19:38

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-04-23T18:11:43-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '17ea209d-ff26-4ff3-8dfc-53375d88057a' User entered 'No (N)'	System	29 Apr 2021 16:19:38

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-04-23T18:11:46-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: '17ea209d-ff26-4ff3-8dfc-53375d88057a' User entered '23 Apr 2021 18:11:46'	System	29 Apr 2021 16:19:38
	System	29 Apr 2021 16:19:38

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-04-29T12:16:22-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a7fe1a9d-6a3a-4d62-8a3a-dc1e66415df8'	System	29 Apr 2021 16:19:40
User entered 'No (N)'	System	29 Apr 2021 16:19:40

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

Have you been exposed to someone with 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 (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-04-29T12:16:23-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a7fe1a9d-6a3a-4d62-8a3a-dc1e66415df8'	System	29 Apr 2021 16:19:40
User entered 'No (N)'	System	29 Apr 2021 16:19:40

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-04-29T12:16:25-04:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'a7fe1a9d-6a3a-4d62-8a3a-dc1e66415df8'	System	29 Apr 2021 16:19:40
User entered '29 Apr 2021 12:16:25'	System	29 Apr 2021 16:19:40

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '11 Oct 2022 00:01'	System	19 Nov 2020 16:48:49

US3402316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:48:49
Amendment Manager: User entered '15 Oct 2022 23:59'	System	19 Nov 2020 16:48:49

US3402316

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:36:03

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 21:51:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-03-04T12:00:42-05:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'dcd0c87b-f47b-494d-ab96-465e02f0e1df' User entered 'No (N)'	System	04 Mar 2021 17:01:44
	System	04 Mar 2021 17:01:44

US3402316

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:36:03

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:51:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4101E41A-2B36-4F22-8606-195A742ABAB5)', Time: '2021-03-04T12:00:45-05:00', User OID: 'PatientReportedOutcome (US3402316)', ODM File OID: 'dcd0c87b-f47b-494d-ab96-465e02f0e1df' User entered '04 Mar 2021 12:00:45'	System	04 Mar 2021 17:01:44
	System	04 Mar 2021 17:01:44

US3402316

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:26:23
User entered 'No (N)'	Jennifer Molstead (b) (4)	07 Dec 2020 20:33:57

US3402316

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:26:23
User entered empty.	Jennifer Molstead (b) (4)	07 Dec 2020 20:33:57

US3402316

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:26:23
User entered empty.	Jennifer Molstead (b) (4)	07 Dec 2020 20:33:57

US3402316

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:26:23
User entered 'Subject in Convalescent phase' reason for change: Data Entry Error	(b) (4)	08 Dec 2020 23:49:12
User entered empty.	Jennifer Molstead (b) (4)	07 Dec 2020 20:33:57
	(b) (4)	

US3402316

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:26:23
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	07 Dec 2020 20:34:04

US3402316

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:57:42
User entered 'I'	System	07 Dec 2020 20:34:04

US3402316

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	07 Dec 2020 20:40:37
	(b) (4)	

US3402316

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered '7 Dec 2020'	Traci Hull (b) (4)	07 Dec 2020 20:40:37
	(b) (4)	

US3402316

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	07 Dec 2020 20:40:37
	(b) (4)	

US3402316

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered empty.	Traci Hull (b) (4)	07 Dec 2020 20:40:37
	(b) (4)	

US3402316

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:09:54
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Dec 2020 20:40:42

US3402316

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User entered 'I'	System	07 Dec 2020 20:40:42

US3402316

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Feb 2021 17:23:56
	(b) (4)	

US3402316

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	24 Feb 2021 17:24:11
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	24 Feb 2021 17:24:11
User entered '8 Jan 2021' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	24 Feb 2021 17:24:11
	(b) (4)	
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	24 Feb 2021 17:23:56
User entered '8 Feb 2021'	Jennifer Molstead (b) (4)	24 Feb 2021 17:23:56
	(b) (4)	

US3402316

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:09:54
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4) (b) (4)	24 Feb 2021 17:23:56

US3402316

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	24 Feb 2021 17:23:56
	(b) (4)	

US3402316

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Feb 2021 17:24:18
	(b) (4)	

US3402316

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User entered 'I'	System	24 Feb 2021 17:24:18

US3402316

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:09:54
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	24 Feb 2021 17:26:25

US3402316

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered '5 Feb 2021'	Jennifer Molstead (b) (4)	24 Feb 2021 17:26:25
	(b) (4)	

US3402316

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4) [REDACTED]	26 Apr 2021 23:09:54
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4) [REDACTED]	24 Feb 2021 17:26:25

US3402316

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	24 Feb 2021 17:26:25
	(b) (4)	

US3402316

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	29 Apr 2021 18:53:26
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:09:54
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	24 Feb 2021 17:26:31

US3402316

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:26
User entered 'I'	System	24 Feb 2021 17:26:31

US3402316

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User closed query 'Per CDM: Please complete vital signs under Visit 4 folder. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 12:39:38
Query 'Per CDM: Please complete vital signs under Visit 4 folder. Thank you. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 13:51:34
User opened query 'Per CDM: Please complete vital signs under Visit 4 folder. Thank you. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:02:47
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Feb 2021 13:28:09

US3402316

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered '24 Feb 2021'	(b) (4)	25 Feb 2021 13:28:09
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	25 Feb 2021 13:28:09

US3402316

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User entered 'VISIT4'	System	25 Feb 2021 13:28:09

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:52:04
	(b) (4)	

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User entered empty.	System	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User entered empty.	System	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User entered empty.	System	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User entered empty.	System	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User entered empty.	System	31 Mar 2021 13:52:04

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11

US3402316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11

US3402316

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Yes (Y)'	(b) (4)	25 Feb 2021 13:28:15
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered '24 Feb 2021'	(b) (4)	25 Feb 2021 13:28:15
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:29:22

US3402316

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:29:22

US3402316

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered '15:25'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 19:29:22

US3402316

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User entered '24 Feb 2021 15:25'	System	17 Mar 2021 19:29:22

US3402316

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Yes (Y)'	(b) (4)	25 Feb 2021 13:28:19
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:11
User entered 'I'	System	25 Feb 2021 13:28:19

US3402316

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	06 Apr 2021 16:11:55
	(b) (4)	

US3402316

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered '6 Apr 2021'	Tammy Kohn (b) (4)	06 Apr 2021 16:11:55
	(b) (4)	

US3402316

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	06 Apr 2021 16:11:55
	(b) (4)	

US3402316

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	06 Apr 2021 16:11:55
	(b) (4)	

US3402316

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	06 Apr 2021 16:12:32
	(b) (4)	

US3402316

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 16:12:32

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:03

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:30:34
User closed query 'The illness visit was on 14-OCT-20 but date of contact is noted as 16-OCT-20.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 19:30:33
Query 'The illness visit was on 14-OCT-20 but date of contact is noted as 16-OCT-20.' answered with 'Updated' (Site from CRA).	Jennifer Molstead (b) (4)	07 Nov 2020 14:19:16
DataPoint Un-verified.	(b) (4)	
	Jennifer Molstead (b) (4)	07 Nov 2020 14:19:11
User entered '14 Oct 2020' reason for change: Per Query Resolution	(b) (4)	
	Jennifer Molstead (b) (4)	07 Nov 2020 14:19:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:56:53
User opened query 'The illness visit was on 14-OCT-20 but date of contact is noted as 16-OCT-20.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 23:55:06
User entered '16 Oct 2020'	Traci Hull (b) (4)	16 Oct 2020 17:00:44
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:03

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:56:53
User entered '14:00'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 17:00:44

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:03

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:36
User entered '14 Oct 2020 14:00'	System	07 Nov 2020 14:19:11
User entered '16 Oct 2020 14:00'	System	16 Oct 2020 17:00:44

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:03

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:56:53
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 17:00:44

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:03

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:56:53
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 17:00:44

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User closed query 'Per source, symptoms started on 09-OCT-20 (Day 1). Please review and update symptom log.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:31:57
User entered 'Day 2 (Day 2)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:27:26
Query 'Per source, symptoms started on 09-OCT-20 (Day 1). Please review and update symptom log.' answered with 'Symptoms started 13Oct2020 will update source and symptoms log.' (Site from CRA).	Jennifer Molstead (b) (4)	07 Nov 2020 14:21:16
User opened query 'Per source, symptoms started on 09-OCT-20 (Day 1). Please review and update symptom log.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 00:05:36
User entered 'Day 1 (Day 1)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '14 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:26:14
DataPoint Un-verified.	(b) (4) Jennifer Molstead (b) (4)	07 Nov 2020 14:21:24
User entered '13 Oct 2020' reason for change: Per Query Resolution	(b) (4) Jennifer Molstead (b) (4)	07 Nov 2020 14:21:24
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User closed query 'Per ETRTR: Please confirm first day of Symptoms is 14Oct20. If subject informed of Symptoms onset previous to Illness Visit, please add Symptoms log entries and update AE "Start date" data point, thanks' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 03:14:44
Query 'Per ETRTR: Please confirm first day of Symptoms is 14Oct20. If subject informed of Symptoms onset previous to Illness Visit, please add Symptoms log entries and update AE "Start date" data point, thanks' answered with 'correct as is' (Site from CRA).	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:15:57
User opened query 'Per ETRTR: Please confirm first day of Symptoms is 14Oct20. If subject informed of Symptoms onset previous to Illness Visit, please add Symptoms log entries and update AE "Start date" data point, thanks' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:44:32
User entered '14 Oct 2020'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 17:02:16

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '100'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	16 Oct 2020 17:02:16

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.6' F	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:22:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 3 (Day 3)' reason for change: Per Query Resolution	(b) (4)	
	Jennifer Molstead (b) (4)	07 Nov 2020 14:27:26
User entered 'Day 2 (Day 2)'	(b) (4)	
	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:02:21
User entered '15 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:26:14
User entered '14 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:21:38
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '15 Oct 2020'	Traci Hull (b) (4)	16 Oct 2020 17:02:55

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:02:22
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:02:24
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '99'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	16 Oct 2020 17:02:55

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:02:36
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '97.8' F	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:02:27
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:02:48
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:02:50
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:02:52
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:02:54
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:02:56
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:02:58
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:02:59
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:03:01
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:03:03
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:03:04
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:04:05
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:04:07
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:04:09
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:04:12
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	16 Oct 2020 17:02:55
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 4 (Day 4)' reason for change: Per Query Resolution	(b) (4)	07 Nov 2020 14:27:26
User entered 'Day 3 (Day 3)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '16 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:26:14
User entered '15 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:21:54
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '16 Oct 2020'	Traci Hull (b) (4)	21 Oct 2020 11:41:32

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '99'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	21 Oct 2020 11:41:32

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '97.7' F	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:41:32
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 5 (Day 5)' reason for change: Per Query Resolution	(b) (4)	07 Nov 2020 14:27:26
User entered 'Day 4 (Day 4)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '17 Oct 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	07 Nov 2020 14:26:14
User entered '16 Oct 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	07 Nov 2020 14:22:57
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '17 Oct 2020'	Traci Hull (b) (4)	21 Oct 2020 11:42:17

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '100'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	21 Oct 2020 11:42:17

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '97.6' F	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:42:17
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 6 (Day 6)' reason for change: Per Query Resolution	(b) (4)	07 Nov 2020 14:27:26
User entered 'Day 5 (Day 5)'	Jennifer Molstead (b) (4)	21 Oct 2020 11:43:00
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '18 Oct 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	07 Nov 2020 14:26:14
User entered '17 Oct 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	07 Nov 2020 14:23:11
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '18 Oct 2020'	Traci Hull (b) (4)	21 Oct 2020 11:43:00

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	21 Oct 2020 11:43:00

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.5' F	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:43:00
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 7 (Day 7)' reason for change: Per Query Resolution	(b) (4)	07 Nov 2020 14:27:26
User entered 'Day 6 (Day 6)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '19 Oct 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	07 Nov 2020 14:26:14
User entered '18 Oct 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	07 Nov 2020 14:23:26
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '19 Oct 2020'	Traci Hull (b) (4)	21 Oct 2020 11:44:19

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '100'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	21 Oct 2020 11:44:19

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '97.7' F	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:44:19
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 8 (Day 8)' reason for change: Per Query Resolution	(b) (4)	07 Nov 2020 14:27:26
User entered 'Day 7 (Day 7)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '20 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:26:14
User entered '19 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:23:42
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '20 Oct 2020'	Traci Hull (b) (4)	21 Oct 2020 11:45:01

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '99'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	21 Oct 2020 11:45:01

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.5' F	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:45:01
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 9 (Day 9)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:27:26
User closed query 'Please enter all missing dates. As a reminder symptom log is to be entered within 24 hrs of call completion. Subject is required to continue daily calls until symptoms resolve or Illness D14 (counting from actual Illness D1 visit) whichever is later.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 03:15:06
Query 'Please enter all missing dates. As a reminder symptom log is to be entered within 24 hrs of call completion. Subject is required to continue daily calls until symptoms resolve or Illness D14 (counting from actual Illness D1 visit) whichever is later.' answered with 'correct as is.' (Site from CRA).	Traci Hull (b) (4) (b) (4)	26 Oct 2020 14:29:17
User opened query 'Please enter all missing dates. As a reminder symptom log is to be entered within 24 hrs of call completion. Subject is required to continue daily calls until symptoms resolve or Illness D14 (counting from actual Illness D1 visit) whichever is later.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 00:27:07
User entered 'Day 8 (Day 8)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:39:39

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '21 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:26:14
User entered '20 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:23:56
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '21 Oct 2020'	Traci Hull (b) (4)	22 Oct 2020 11:39:39

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '99'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	22 Oct 2020 11:39:39

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.6' F	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:39:39
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 14 Oct 2020 symptom log on log line 9. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:51:21
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 14 Oct 2020 symptom log on log line 9. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	20 Apr 2021 11:54:43
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 14 Oct 2020 symptom log on log line 9. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:15:11
User entered 'Day 10 (Day 10)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:27:26
User entered 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:16:50

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '22 Oct 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	07 Nov 2020 14:26:14
User entered '21 Oct 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	07 Nov 2020 14:24:08
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '22 Oct 2020'	Traci Hull (b) (4)	26 Oct 2020 12:16:50

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '99'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	26 Oct 2020 12:16:50

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.4' F	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:13:41
DataPoint Un-verified.	Jennifer Molstead (b) (4)	20 Apr 2021 11:54:10
User entered 'None (None)' reason for change: Per Query Resolution	(b) (4)	20 Apr 2021 11:54:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:16:50

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:16:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:27:26
User entered 'Day 10 (Day 10)'	(b) (4)	
	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '23 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:26:14
User entered '22 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:24:22
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '23 Oct 2020'	Traci Hull (b) (4)	26 Oct 2020 12:17:35

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	26 Oct 2020 12:17:35

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '97.4' F	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:17:35
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:34:21
User entered 'Day 11 (Day 11)'	(b) (4)	
	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:06:56
User closed query 'Per CDM: Per sponsor review, please verify data and consider updating 'Date' to 24Oct2020.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 07:59:12
Query 'Per CDM: Per sponsor review, please verify data and consider updating 'Date' to 24Oct2020.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	15 Mar 2021 17:00:48
DataPoint Un-verified.	(b) (4)	
	Tammy Kohn (b) (4)	15 Mar 2021 16:59:48
User entered '24 Oct 2020' reason for change: Per Query Resolution	(b) (4)	
	Tammy Kohn (b) (4)	15 Mar 2021 16:59:48
User opened query 'Per CDM: Per sponsor review, please verify data and consider updating 'Date' to 24Oct2020.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	14 Mar 2021 20:02:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '22 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:25:16
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Jennifer Molstead (b) (4)	07 Nov 2020 14:24:42
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '24 Oct 2020'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '99'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	26 Oct 2020 12:18:07

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:47:47
User closed query 'Per CDM: It appears temperature of 8.7 F is rather low. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 10:07:34
Query 'Per CDM: It appears temperature of 8.7 F is rather low. Please review and update accordingly.' answered with 'Updated' (Site from DM).	Jennifer Molstead (b) (4)	31 Dec 2020 21:25:27
DataPoint Un-verified.	(b) (4) Jennifer Molstead (b) (4)	31 Dec 2020 21:25:20
User entered '98.7' F reason for change: Data Entry Error	Jennifer Molstead (b) (4)	31 Dec 2020 21:25:20
User opened query 'Per CDM: It appears temperature of 8.7 F is rather low. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 22:02:27
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '8.7' F	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:18:07

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 13 (Day 13)' reason for change: Per Query Resolution	(b) (4) Jennifer Molstead (b) (4)	07 Nov 2020 14:34:21
User entered 'Day 12 (Day 12)'	(b) (4) Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '25 Oct 2020'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '100'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	26 Oct 2020 12:18:36

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.6' F	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:18:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 14 (Day 14)' reason for change: Per Query Resolution	(b) (4) Jennifer Molstead (b) (4)	07 Nov 2020 14:34:21
User entered 'Day 13 (Day 13)'	(b) (4) Traci Hull (b) (4)	27 Oct 2020 11:18:59

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '26 Oct 2020'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '99'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	27 Oct 2020 11:18:59

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.9' F	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'Mild (Mild)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 11:18:59
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 15 (Day 15)' reason for change:	(b) (4)	
Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:34:21
User entered 'Day 14 (Day 14)'	(b) (4)	
	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '27 Oct 2020'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '100'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	02 Nov 2020 12:35:07

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.1' F	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:07
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 16 (Day 16)' reason for change:	(b) (4)	
Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:34:21
User entered 'Day 15 (Day 15)'	(b) (4)	
	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '28 Oct 2020'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '100'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	02 Nov 2020 12:35:52

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.2' F	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:35:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 17 (Day 17)' reason for change: Per Query Resolution	(b) (4) Jennifer Molstead (b) (4)	07 Nov 2020 14:34:21
User entered 'Day 16 (Day 16)'	(b) (4) Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '29 Oct 2020'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '100'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	02 Nov 2020 12:36:29

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.7' F	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:36:29
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 18 (Day 18)' reason for change:	(b) (4)	
Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:34:21
User entered 'Day 17 (Day 17)'	(b) (4)	
	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '30 Oct 2020'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '100'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	02 Nov 2020 12:37:16

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.2' F	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:16
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 19 (Day 19)' reason for change: Per Query Resolution	(b) (4) Jennifer Molstead (b) (4)	07 Nov 2020 14:34:21
User entered 'Day 18 (Day 18)'	(b) (4) Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '31 Oct 2020'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '99'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	02 Nov 2020 12:37:50

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.3' F	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:37:50
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 20 (Day 20)' reason for change: Per Query Resolution	(b) (4) Jennifer Molstead (b) (4)	07 Nov 2020 14:34:21
User entered 'Day 19 (Day 19)'	(b) (4) Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:29:40
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 14:40:07
User entered '01 Nov 2020' reason for change: New Information	(b) (4) Traci Hull (b) (4)	11 Nov 2020 14:40:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '1 Nov 2020'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 12:38:20

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '100'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	02 Nov 2020 12:38:20

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.1' F	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	02 Nov 2020 12:38:20
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 21 (Day 21)' reason for change:	(b) (4)	
Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:34:21
User entered 'Day 20 (Day 20)'	(b) (4)	
	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:29:36
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 14:40:07
User entered '02 Nov 2020' reason for change: New Information	(b) (4) Traci Hull (b) (4)	11 Nov 2020 14:40:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '2 Nov 2020'	Traci Hull (b) (4) (b) (4)	03 Nov 2020 20:58:22

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '99'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	03 Nov 2020 20:58:22

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '98.3' F	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:22
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 22 (Day 22)' reason for change: Per Query Resolution	(b) (4) Jennifer Molstead (b) (4)	07 Nov 2020 14:34:21
User entered 'Day 21 (Day 21)'	(b) (4) Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:29:27
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 14:40:24
User entered '03 Nov 2020' reason for change: New Information	(b) (4) Traci Hull (b) (4)	11 Nov 2020 14:40:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '3 Nov 2020'	Traci Hull (b) (4) (b) (4)	03 Nov 2020 20:58:52

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '0'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '100'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	03 Nov 2020 20:58:52

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered '97.8' F	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 00:22:37
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 00:05:40
User entered 'None (None)'	Traci Hull (b) (4)	03 Nov 2020 20:58:52
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 1 (Day 1)'	(b) (4) Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User closed query 'Per CDM: per sponsor review Covid-19 AE start date is entered as 12-Oct-20. Please enter any reported symptoms in log for Day 1 12-Oct and Day 2 13-Oct or mark not done' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:50:48
Query 'Per CDM: per sponsor review Covid-19 AE start date is entered as 12-Oct-20. Please enter any reported symptoms in log for Day 1 12-Oct and Day 2 13-Oct or mark not done' answered with 'NOT DONE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Nov 2020 13:26:47
User opened query 'Per CDM: per sponsor review Covid-19 AE start date is entered as 12-Oct-20. Please enter any reported symptoms in log for Day 1 12-Oct and Day 2 13-Oct or mark not done' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 11:35:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '13 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:36:30

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:36:30

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:36:30

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	07 Nov 2020 14:36:30

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:36:30

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:36:30

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:36:30

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'Moderate (Moderate)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:36:30

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:36:30
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:36:30

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 23 (Day 23)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '04 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '100'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '97.8' F	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:37:58
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:37:58
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:37:58
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:37:58
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:37:58
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:37:58
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:37:58
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:37:58

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:37:58
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:37:58
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 24 (Day 24)'	(b) (4) Jennifer Molstead (b) (4)	07 Nov 2020 14:38:49

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '05 Nov 2020'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:38:49

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:38:49

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Nov 2020 05:16:40
User entered '99'	Jennifer Molstead (b) (4)	07 Nov 2020 14:38:49
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	07 Nov 2020 14:38:49

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '98.2' F	Jennifer Molstead (b) (4)	07 Nov 2020 14:38:49
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:38:49
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:38:49
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:38:49

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:38:49
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:38:49

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:38:49
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:38:49

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:38:49

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:38:49
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:38:49

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:38:49
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:38:49
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:38:49

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:38:49
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 14:38:49

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	07 Nov 2020 14:38:49
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 25 (Day 25)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '06 Nov 2020'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered '0'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '100'	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 01:17:10

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	10 Nov 2020 01:17:10

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '98.1' F	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 01:17:10

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:17:10
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 26 (Day 26)'	(b) (4) Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '07 Nov 2020'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 01:18:33

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '99'	Jennifer Molstead (b) (4)	(b) (4)

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	10 Nov 2020 01:18:33

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Nov 2020 05:16:40
User entered '97.8' F	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 01:18:33

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:18:33
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 27 (Day 27)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '08 Nov 2020'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered '0'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '100'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	10 Nov 2020 01:20:05

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '98.7' F	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 05:16:40
	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:20:05
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Day 28 (Day 28)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '09 Nov 2020'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered '0'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered '100'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User entered '%'	System	10 Nov 2020 01:21:41

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered '97.7' F	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 01:21:41

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 05:16:40
	(b) (4)	10 Nov 2020 01:21:41

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 01:21:41

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 01:21:41

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (28)

Generated On: 11 Aug 2021 22:36:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:57:47
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	10 Nov 2020 05:16:40
User entered 'None (None)'	Jennifer Molstead (b) (4)	10 Nov 2020 01:21:41
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:03

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:21:09
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	21 Oct 2020 00:54:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:03

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:09
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:54:36

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:03

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:09
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) (6)	21 Oct 2020 11:29:46
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 'Already Completed' (Site from System).	Jennifer Molstead (b) (4)	21 Oct 2020 00:54:52
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	21 Oct 2020 00:54:36
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:54:36

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:03

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:21:09
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	21 Oct 2020 00:54:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:03

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:09
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:54:36

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:03

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:09
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:54:36

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:03

[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)	02 May 2021 23:58:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:09
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:54:36

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:03

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 00:21:09
User entered empty.	Jennifer Molstead (b) (4)	21 Oct 2020 00:54:36
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:03

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:09
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:54:36

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:36:03

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:04
User entered 'I'	System	21 Oct 2020 00:54:36

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4)	24 Oct 2020 00:27:27
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

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)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4)	24 Oct 2020 00:27:27
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4)	24 Oct 2020 00:27:27
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4)	24 Oct 2020 00:27:27
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4)	24 Oct 2020 00:27:27
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:21:51
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 00:21:51
	Jennifer Molstead (b) (4)	24 Oct 2020 00:27:27
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	06 Nov 2020 00:21:51
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 00:21:51
	Jennifer Molstead (b) (4)	24 Oct 2020 00:27:27
	(b) (4)	

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:36:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 00:21:51
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:27:27

US3402316

Folder: Covid-19 Assessment 14 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:36:03

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:58:39
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:52:11
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	08 Dec 2020 23:48:20

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:36:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:55
	(b) (4)	

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:36:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 04:48:18
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:56:55

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:36:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 04:48:21
User entered '16 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:56:55

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:36:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:56:55

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:36:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 04:54:18
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:56:55

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:36:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 04:54:18
User entered '18 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:56:55

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:36:03

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Please verify and enter D9 saliva sample collection' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 04:35:18
Query 'Please verify and enter D9 saliva sample collection' answered with 'Updated' (Site from CRA).	Jennifer Molstead (b) (4)	28 Oct 2020 13:42:34
User opened query 'Please verify and enter D9 saliva sample collection' (Site from CRA).	(b) (4)	
User opened query 'Please verify and enter D9 saliva sample collection' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 00:09:11
User accepted default value 'Day 7 (Day 7)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:55
	(b) (4)	

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:36:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 04:54:18
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:56:55

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:36:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 04:54:18
User entered '20 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:56:55

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:36:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:55
	(b) (4)	

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:36:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 04:54:18
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	28 Oct 2020 13:43:21
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 11:27:56
Query 'Data is required. Please complete.' answered with 'will update' (Site from System).	Jennifer Molstead (b) (4)	21 Oct 2020 00:57:01
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 00:56:55
User entered empty.	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:55
	(b) (4)	

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:36:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 04:54:18
User entered '22 Oct 2020' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 13:43:21
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:56:55

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:36:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:55
	(b) (4)	

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:36:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 04:54:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	02 Nov 2020 12:39:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 11:27:58
Query 'Data is required. Please complete.' answered with 'will update' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:57:08
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 00:56:55
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:56:55

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:36:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 04:54:18
User entered '27 Oct 2020' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	02 Nov 2020 12:39:00
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	21 Oct 2020 00:56:55

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:36:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:55
	(b) (4)	

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:36:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 04:04:52
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 04:02:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:54:18
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	03 Nov 2020 20:57:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 11:28:01
Query 'Data is required. Please complete.' answered with 'will update' (Site from System).	Jennifer Molstead (b) (4)	21 Oct 2020 00:57:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 00:56:55
User entered empty.	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:55
	(b) (4)	

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:36:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 04:04:56
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10NOV2020 is reported under Convalescence Visit Day 28 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.	(b) (4), (b) (6)	20 Nov 2020 07:12:37
' (Site from DM).		
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10NOV2020 is reported under Convalescence Visit Day 28 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.	Tammy Kohn (b) (4)	19 Nov 2020 13:55:59
	(b) (4)	
' answered with 'DATA UPDATED' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10NOV2020 is reported under Convalescence Visit Day 28 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.	(b) (4), (b) (6)	18 Nov 2020 06:26:48
' (Site from DM).		
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 14:40:49
	(b) (4)	
User entered '03 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 14:40:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 04:54:18
User entered '3 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	03 Nov 2020 20:57:13
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:55
	(b) (4)	

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:36:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:55
	(b) (4)	

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:36:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 04:01:28
DataPoint Un-verified.	Tammy Kohn (b) (4)	19 Nov 2020 13:55:25
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	19 Nov 2020 13:55:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:54:18
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 11:28:04
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'will update' (Site from System).	Jennifer Molstead (b) (4)	21 Oct 2020 00:57:19
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 00:56:55
User entered empty.	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:55
	(b) (4)	

US3402316

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:36:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 04:01:30
DataPoint Un-verified.	Tammy Kohn (b) (4)	19 Nov 2020 13:55:25
	(b) (4)	
User entered '10 Nov 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	19 Nov 2020 13:55:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:54:18
User entered empty.	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:55
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:26:45
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:55:08

US3402316

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:26:45
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	21 Oct 2020 00:55:08
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:26:45
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:55:08
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User entered 'SICKD1'	System	21 Oct 2020 00:55:08

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:13
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:13
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '14:00'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:13
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User entered '14 Oct 2020 14:00'	System	21 Oct 2020 00:56:13

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:32:07
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:13
DataPoint set to visible.	(b) (4)	
	System	21 Oct 2020 00:55:08

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:13
DataPoint set to visible.	(b) (4)	21 Oct 2020 00:55:08
	System	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '98.6' F	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:13
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Oral (Oral)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:13
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:13
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '72'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:13
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User entered 'bpm'	System	21 Oct 2020 00:56:13

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '14'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:13
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User entered 'breaths/min'	System	21 Oct 2020 00:56:13

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '129'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:13
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User entered 'mmHg'	System	21 Oct 2020 00:56:13

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '83'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:13
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User entered 'mmHg'	System	21 Oct 2020 00:56:13

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25

US3402316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25

US3402316

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:24
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:24
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:36:03

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	21 Oct 2020 00:56:32
	(b) (4)	

US3402316

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:36:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:34:25
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	05 Nov 2020 23:34:27
	(b) (4)	21 Oct 2020 00:56:32

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 00:24:01
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 11:50:10

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 00:24:01
User entered '10 Nov 2020'	Jennifer Molstead (b) (4)	13 Nov 2020 11:50:10
	(b) (4)	

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 00:24:01
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 11:50:10

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User entered 'SICKD28'	System	13 Nov 2020 11:50:10

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 00:36:23
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:20
	(b) (4)	

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4), (b) (6)	31 Dec 2020 00:36:23
User entered '10 Nov 2020'	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:20

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User closed query 'Per source, the time point was 15:26. Please review and update entries.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 18:07:29
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 18:07:25
Query 'Per source, the time point was 15:26. Please review and update entries.' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	31 Dec 2020 21:24:53
DataPoint Un-verified.	(b) (4)	
User entered '15:26' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	31 Dec 2020 21:24:45
DataPoint Verified.	(b) (4), (b) (6)	31 Dec 2020 00:36:23
User opened query 'Per source, the time point was 15:26. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	31 Dec 2020 00:36:18
User entered '15:20'	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:20
	(b) (4)	

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User entered '10 Nov 2020 15:26'	System	31 Dec 2020 21:24:45
User entered '10 Nov 2020 15:20'	System	13 Nov 2020 11:51:20

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 00:36:23
User entered '163.4' cm	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:20
DataPoint set to visible.	(b) (4)	
	System	13 Nov 2020 11:50:10

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 00:36:23
User entered '83.2' kg	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:20
DataPoint set to visible.	(b) (4)	
	System	13 Nov 2020 11:50:10

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4), (b) (6)	31 Dec 2020 00:36:23
User entered '36.8' C	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:20

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 00:36:23
User entered 'Oral (Oral)'	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:20
	(b) (4)	

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 00:36:23
User entered empty.	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:20
	(b) (4)	

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 00:36:23
User entered '70'	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:20
	(b) (4)	

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User entered 'bpm'	System	13 Nov 2020 11:51:20

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 00:36:23
User entered '14'	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:20
	(b) (4)	

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User entered 'breaths/min'	System	13 Nov 2020 11:51:20

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '104'	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:20
	(b) (4)	

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User entered 'mmHg'	System	13 Nov 2020 11:51:20

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '68'	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:20
	(b) (4)	

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User entered 'mmHg'	System	13 Nov 2020 11:51:20

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 00:17:28
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:50
	(b) (4)	

US3402316

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4), (b) (6)	31 Dec 2020 00:17:28
User entered '10 Nov 2020'	Jennifer Molstead (b) (4)	13 Nov 2020 11:51:50

US3402316

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:36:03

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 00:22:08
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	13 Nov 2020 11:52:01

US3402316

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:36:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:02:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4), (b) (6)	31 Dec 2020 00:22:08
User entered '10 Nov 2020'	Jennifer Molstead (b) (4)	13 Nov 2020 11:52:01

US3402316

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

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Yes (Y)'	(b) (4)	25 Feb 2021 13:29:18
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

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

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered '24 Feb 2021'	(b) (4)	
	Traci Hull (b) (4)	25 Feb 2021 13:29:18
	(b) (4)	

US3402316

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

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	25 Feb 2021 13:29:18

US3402316

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

Form: Visit Date

Generated On: 11 Aug 2021 22:36:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User entered 'UNBLND_DECIDE'	System	25 Feb 2021 13:29:18

US3402316

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:03

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered '06 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	25 Feb 2021 13:33:29
	(b) (4)	

US3402316

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:03

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:01:17

US3402316

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Yes (Y)'	(b) (4)	25 Feb 2021 13:33:29
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:03

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
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 12:01:17

US3402316

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:03

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered '24 Feb 2021'	(b) (4)	
	Traci Hull (b) (4)	25 Feb 2021 13:33:29
	(b) (4)	

US3402316

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Traci Hull (b) (4)	25 Feb 2021 13:33:29

US3402316

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Traci Hull (b) (4)	25 Feb 2021 13:33:29

US3402316

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:03

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Traci Hull (b) (4)	25 Feb 2021 13:33:29

US3402316

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:03

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'No (N)'	(b) (4)	25 Feb 2021 13:33:29
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:03

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User entered empty.	System	25 Feb 2021 13:33:29

US3402316

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:03

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User entered empty.	System	25 Feb 2021 13:33:29

US3402316

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Yes (Y)'	(b) (4)	25 Feb 2021 13:33:40
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered '24 Feb 2021'	(b) (4)	
	Traci Hull (b) (4)	25 Feb 2021 13:33:40
	(b) (4)	

US3402316

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered '15:25'	(b) (4)	25 Feb 2021 13:33:40
	Traci Hull (b) (4)	
	(b) (4)	

US3402316

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User entered '24 Feb 2021 15:25'	System	25 Feb 2021 13:33:40

US3402316

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:36:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	25 Feb 2021 13:33:53

US3402316

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:36:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered '24 Feb 2021'	(b) (4)	
	Traci Hull (b) (4)	25 Feb 2021 13:33:53
	(b) (4)	

US3402316

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:36:03

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
User entered '15:23'	(b) (4)	
	Traci Hull (b) (4)	25 Feb 2021 13:33:53
	(b) (4)	

US3402316

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:36:03

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:36
User entered '24 Feb 2021 15:23'	System	25 Feb 2021 13:33:53

US3402316

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:36:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:06
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:58:37
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'ADDED AE FOR FATIGUE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:12:56
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 11:15:28
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:45:41
User closed query 'Per source, pregnancy was noted. Per protocol, pregnancy is to be reported to sponsor within 24 hours. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 03:22:45
Query 'Per source, pregnancy was noted. Per protocol, pregnancy is to be reported to sponsor within 24 hours. Please review and update entries.' answered with 'UPDATED' (Site from CRA).	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:35
User opened query 'Per source, pregnancy was noted. Per protocol, pregnancy is to be reported to sponsor within 24 hours. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 04:15:46
Query 'Per source, pregnancy was noted. Please protocol pregnancy is to be reported to sponsor within 24 hours.' canceled (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 04:14:10

US3402316

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:36:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per source, pregnancy was noted. Please protocol pregnancy is to be reported to sponsor within 24 hours.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 04:13:56
	(b) (4), (b) (6)	05 Nov 2020 22:38:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Traci Hull (b) (4)	16 Sep 2020 18:14:46
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	10 Aug 2020 20:53:48
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 18:17:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 18:17:39
Data point term sent to Coder	System	16 Sep 2020 18:16:50
User entered 'URINARY TRACT INFECTION'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered 'Yes (Y)'	Traci Hull (b) (4)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered 'No (N)'	(b) (4), (b) (6)	
	Traci Hull (b) (4)	16 Sep 2020 18:16:41
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:29:12
User closed query 'Per source (AE log), start date was 09-SEP-20. Please clarify.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 19:29:11
Query 'Per source (AE log), start date was 09-SEP-20. Please clarify.' answered with 'Updated' (Site from CRA).	Jennifer Molstead (b) (4)	07 Nov 2020 14:43:49
DataPoint Un-verified.	(b) (4)	
	Jennifer Molstead (b) (4)	07 Nov 2020 14:43:39
User entered '09 Sep 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:43:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:01:50
User opened query 'Per source (AE log), start date was 09-SEP-20. Please clarify.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 22:50:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	16 Sep 2020 23:49:17
Comment added 'CORRECT AS IS'.	Traci Hull (b) (4)	16 Sep 2020 18:19:32
	(b) (4)	
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Sep 2020 18:16:54
User closed query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).		16 Sep 2020 18:16:54
User entered '10 Sep 2020' reason for change: Data Entry Error	Traci Hull (b) (4)	16 Sep 2020 18:16:54
	(b) (4)	
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	16 Sep 2020 18:16:41
User entered '9 Sep 2020'	Traci Hull (b) (4)	16 Sep 2020 18:16:41
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

2493 of 2865

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User entered empty.	System	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered '16 Sep 2020'	Traci Hull (b) (4)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User entered empty.	System	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
	(b) (4), (b) (6)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Traci Hull (b) (4)	16 Sep 2020 18:16:41
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:01:50
User entered '0'	Traci Hull (b) (4)	16 Sep 2020 18:16:41
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered '0'	Traci Hull (b) (4)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered '0'	(b) (4), (b) (6)	
	Traci Hull (b) (4)	16 Sep 2020 18:16:41
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered empty.	(b) (4), (b) (6)	
	Traci Hull (b) (4)	16 Sep 2020 18:16:41
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered empty.	Traci Hull (b) (4)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 23:01:50
	Traci Hull (b) (4)	16 Sep 2020 18:16:41
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered '0'	(b) (4), (b) (6)	
	Traci Hull (b) (4)	16 Sep 2020 18:16:41
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered '0'	Traci Hull (b) (4)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered '0'	Traci Hull (b) (4)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Tammy Kohn (b) (4)	18 Nov 2020 13:51:01
User closed query 'Per CDM Re-Query: per sponsor review, Relationship to both IP and Study Procedure should be recorded as NOT APPLICABLE. Please reconcile' (Site from DM).	(b) (4)	18 Nov 2020 09:37:34
Query 'Per CDM Re-Query: per sponsor review, Relationship to both IP and Study Procedure should be recorded as NOT APPLICABLE. Please reconcile' answered with 'DATA UPDATED' (Site from DM).	(b) (4), (b) (6)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Tammy Kohn (b) (4)	17 Nov 2020 13:11:43
User opened query 'Per CDM Re-Query: per sponsor review, Relationship to both IP and Study Procedure should be recorded as NOT APPLICABLE. Please reconcile' (Site from DM).	(b) (4)	17 Nov 2020 13:11:37
User closed query 'Per CDM: AE start date is 10 SEP 2020 and first dose is recorded as 09 AUG 2020. Per CCGs pg 34, Relationship to IP should be recorded as Not Applicable only if clinical event is prior to first dose. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 14:23:35
Query 'Per CDM: AE start date is 10 SEP 2020 and first dose is recorded as 09 AUG 2020. Per CCGs pg 34, Relationship to IP should be recorded as Not Applicable only if clinical event is prior to first dose. Please review and reconcile.' answered with 'Updated' (Site from DM).	(b) (4)	08 Nov 2020 13:41:33
DataPoint Un-verified.	Jennifer Molstead (b) (4)	07 Nov 2020 14:44:07
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	(b) (4) Jennifer Molstead (b) (4)	07 Nov 2020 14:43:39 07 Nov 2020 14:43:39

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: AE start date is 10 SEP 2020 and first dose is recorded as 09 AUG 2020. Per CCGs pg 34, Relationship to IP should be recorded as Not Applicable only if clinical event is prior to first dose. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:03:18
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:01:50
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 18:29:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 18:29:24
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	Traci Hull (b) (4)	23 Sep 2020 18:29:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Sep 2020 18:16:41
User entered empty.	System	16 Sep 2020 18:16:41
	Traci Hull (b) (4)	16 Sep 2020 18:16:41
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:50
User closed query 'Per CDM: Per previous query, please update Relationship to Study procedure as NOT APPLICABLE. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 18:09:22
Query 'Per CDM: Per previous query, please update Relationship to Study procedure as NOT APPLICABLE. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:51:05
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:50:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:50:31
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:50:24
User entered 'Related (RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:50:24
User opened query 'Per CDM: Per previous query, please update Relationship to Study procedure as NOT APPLICABLE. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:37:27
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:01:50
User entered 'Not Related (NOT RELATED)'	Traci Hull (b) (4) (b) (4)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered 'None (NONE)'	(b) (4), (b) (6)	
	Traci Hull (b) (4)	16 Sep 2020 18:16:41
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered '0'	(b) (4), (b) (6)	
	Traci Hull (b) (4)	16 Sep 2020 18:16:41
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered 'l'	Traci Hull (b) (4)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered '0'	Traci Hull (b) (4)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Traci Hull (b) (4)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
User entered empty.	Traci Hull (b) (4) (b) (4)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	05 Nov 2020 23:01:50
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User entered '0'	System	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05
User entered 'I'	System	16 Sep 2020 18:16:41

US3402316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:05

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:29:46
User entered	System	19 Oct 2020 17:29:40
'USA-US059-2020-mRNA-1273-P301000008'		
User entered 'New'	(b) (4), (b) (6)	19 Oct 2020 17:29:40

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:01:50
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)	29 Oct 2020 17:59:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 17:59:48
Data point term sent to Coder	System	28 Oct 2020 15:18:35
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	28 Oct 2020 15:18:10
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 20:47:38
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	27 Oct 2020 20:46:54
	(b) (4)	
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)	18 Oct 2020 14:48:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Oct 2020 14:48:26
	(b) (4)	
Data point term sent to Coder	System	18 Oct 2020 14:47:20
User entered 'COVID-19'	Jennifer Molstead (b) (4)	18 Oct 2020 14:47:14
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User closed query 'PV Query: Please provide the start date for the event.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:01:00
Query 'PV Query: Please provide the start date for the event.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:22:20
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 00:21:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 00:21:52
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:21:52
User opened query 'PV Query: Please provide the start date for the event.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:49:28
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Oct 2020 14:47:14
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	27 Oct 2020 20:46:54
User entered empty.	System	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:01:50
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.	(b) (4), (b) (6)	03 Nov 2020 22:46:33
' (Site from Safety).		
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Nov 2020 20:48:44
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	02 Nov 2020 20:48:44
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.	Jennifer Molstead (b) (4)	02 Nov 2020 20:48:18
' answered with 'updated' (Site from Safety).	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Nov 2020 20:48:09
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.	(b) (4), (b) (6)	30 Oct 2020 20:25:09
' (Site from Safety).		
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	27 Oct 2020 20:46:54
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	24 Oct 2020 00:21:52
User entered 'Yes (Y)'	System	18 Oct 2020 14:47:14
	Jennifer Molstead (b) (4)	18 Oct 2020 14:47:14
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
User entered '26 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	02 Nov 2020 20:48:09
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User closed query 'PV Query: Please confirm the end date for the event. It is currently reported as 12-Oct-2020, however it is also reported that the subject continued to have symptoms on 15-Oct-2020.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:01:20
Query 'PV Query: Please confirm the end date for the event. It is currently reported as 12-Oct-2020, however it is also reported that the subject continued to have symptoms on 15-Oct-2020.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:22:27
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Oct 2020 00:21:52
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	24 Oct 2020 00:21:52
User entered empty; reason for change Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:21:52
User opened query 'PV Query: Please confirm the end date for the event. It is currently reported as 12-Oct-2020, however it is also reported that the subject continued to have symptoms on 15-Oct-2020.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:50:40
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	18 Oct 2020 14:47:14
User entered '12 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	27 Oct 2020 20:46:54
User entered empty.	System	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
User entered 'No (N)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:21:01
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User closed query 'PV Query: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:01:28
Query 'PV Query: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:22:41
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Oct 2020 00:21:52
User opened query 'PV Query: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:56:27
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Oct 2020 14:47:14
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:01:50
User entered '0' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	28 Oct 2020 15:21:01
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	28 Oct 2020 15:18:10
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	27 Oct 2020 20:46:54
	(b) (4)	
User entered '1' reason for change: New Information	Jennifer Molstead (b) (4)	24 Oct 2020 00:21:52
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	18 Oct 2020 14:47:14
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 01:56:19
User closed query 'Per source marked as not related - Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 01:56:14
Query 'Per source marked as not related - Please verify and update. ' answered with 'data updated' (Site from CRA).	Tammy Kohn (b) (4)	20 Nov 2020 19:05:54
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Tammy Kohn (b) (4)	20 Nov 2020 19:05:44
	(b) (4)	
User opened query 'Per source marked as not related - Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 17:38:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 17:38:16
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:38:13
DataPoint Un-verified.	Jennifer Molstead (b) (4)	19 Nov 2020 11:55:28
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 11:55:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	28 Oct 2020 15:18:10
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	27 Oct 2020 20:46:54
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:47:14
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 01:56:22
User closed query 'Per source marked as not related - Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 01:56:20
Query 'Per source marked as not related - Please verify and update. ' answered with 'data updated' (Site from CRA).	Tammy Kohn (b) (4)	20 Nov 2020 19:05:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Tammy Kohn (b) (4)	20 Nov 2020 19:05:44
	(b) (4)	
User opened query 'Per source marked as not related - Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 17:38:55
DataPoint Un-verified.	Jennifer Molstead (b) (4)	19 Nov 2020 11:55:28
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	Jennifer Molstead (b) (4)	19 Nov 2020 11:55:28
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	28 Oct 2020 15:18:10
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	27 Oct 2020 20:46:54
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:47:14
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User closed query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:02:20
Query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:22:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:21:52
User opened query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:57:46
User entered 'None (NONE)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

None

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Oct 2020 00:25:53
User entered '1' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	24 Oct 2020 00:25:53
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Oct 2020 14:47:14
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:01:50
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 22:46:23
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	02 Nov 2020 20:48:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	02 Nov 2020 20:48:09
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:25:39
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	27 Oct 2020 20:46:54
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:02:52
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'will updatr' (Site from Safety).	Jennifer Molstead (b) (4)	24 Oct 2020 00:23:28
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:53:04
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:01:50
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	27 Oct 2020 20:46:54
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:01:50
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 22:46:20
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	02 Nov 2020 20:48:33
User entered 'SUBJECTHAD DIRECT EXPOSURE TO A PERSON WITH A POSITIVE COVID 19 DIAGNOSIS. THEY WERE BROUGHT IN FOR AN ILLNESS VISIT DUE TO SYMPTOMS. Subject did not use any medication to treat symptoms' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	02 Nov 2020 20:48:09
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:26:19
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	27 Oct 2020 20:46:54
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)	26 Oct 2020 19:03:18

PRODUCTION RELEASE (v12.003
EAB) (1725)

2557 of 2865

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:03:14
User closed query 'PV Query: Please provide the date of the COVID test that the subject took on her own, if known.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:03:11
User closed query 'PV Query: Was the subject tested for COVID-19 by the site? If yes, please provide results and date.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:03:00
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	24 Oct 2020 00:29:37
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	24 Oct 2020 00:28:53
Query 'PV Query: Please provide the date of the COVID test that the subject took on her own, if known.' answered with 'no test was done at outside venue' (Site from Safety).	Jennifer Molstead (b) (4)	24 Oct 2020 00:28:42
Query 'PV Query: Was the subject tested for COVID-19 by the site? If yes, please provide results and date.' answered with 'updated narrative' (Site from Safety).	Jennifer Molstead (b) (4)	24 Oct 2020 00:28:18
User entered 'SUBJECTHAD DIRECT EXPOSURE TO A PERSON WITH A POSITIVE COVID 19 DIAGNOSIS. THEY WERE BROUGHT IN FOR AN ILLNESS VISIT DUE TO SYMPTOMS.' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	24 Oct 2020 00:25:53

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Narrative](#)

Audit	User	Time (GMT)
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)	23 Oct 2020 17:57:04
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:55:00
User opened query 'PV Query: Please provide the date of the COVID test that the subject took on her own, if known.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:51:46
User opened query 'PV Query: Was the subject tested for COVID-19 by the site? If yes, please provide results and date.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:51:27
User entered 'SUBJECTHAD DIRECT EXPOSURE TO A PERSON WITH A POSITIVE COVID 19 DIAGNOSIS. SUBJECT HAD AN OUTSIDE POSITIVE TEST AND PHONED SITE TO REPORT. THEY WERE BROUGHT IN FOR AN ILLNESS VISIT.'	Jennifer Molstead (b) (4)	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 15:21:01
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	(b) (4)	27 Oct 2020 20:46:54
User entered '1'	System	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	27 Oct 2020 20:46:54
User entered 'I'	System	18 Oct 2020 14:47:14

US3402316

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:36:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	28 Oct 2020 15:18:10
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	27 Oct 2020 20:46:54

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 01:40:12
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Pregnancy, LLT: Pregnancy - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 16:21:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 16:21:57
Data point term sent to Coder	System	24 Nov 2020 16:21:26
User entered 'PREGNANCY'	Traci Hull (b) (4)	24 Nov 2020 16:21:21
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered 'Yes (Y)'	Traci Hull (b) (4)	24 Nov 2020 16:21:21
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 06:57:07
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Dec 2020 16:47:55
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	19 Dec 2020 16:47:45
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the Solicited Adverse Reaction per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to "NO". Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 03:01:47
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered '24 Oct 2020'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered '0'	Traci Hull (b) (4)	24 Nov 2020 16:21:21
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered '0'	Traci Hull (b) (4)	24 Nov 2020 16:21:21
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered '0'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered '0'	Traci Hull (b) (4)	24 Nov 2020 16:21:21
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered '0'	Traci Hull (b) (4)	24 Nov 2020 16:21:21
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered '0'	Traci Hull (b) (4)	24 Nov 2020 16:21:21
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered 'Not Related (NOT RELATED)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered 'Not Related (NOT RELATED)'	Traci Hull (b) (4)	24 Nov 2020 16:21:21
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered 'Not Applicable (NOT APPLICABLE)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered 'I'	Traci Hull (b) (4)	24 Nov 2020 16:21:21
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered '0'	Traci Hull (b) (4)	24 Nov 2020 16:21:21
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered '0'	Traci Hull (b) (4)	24 Nov 2020 16:21:21
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Dec 2020 01:40:12
User entered empty.	Traci Hull (b) (4)	24 Nov 2020 16:21:21
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:36:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 16:21:21

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
User closed query 'Fatigue is not reported in source. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 15:18:02
Query 'Fatigue is not reported in source. Please review and update entries.' answered with 'updated' (Site from CRA).	Traci Hull (b) (4)	16 Apr 2021 12:23:36
User opened query 'Fatigue is not reported in source. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 20:17:23

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:26
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 20:14:53
Data point term sent to Coder	(b) (4)	
User entered 'FATIGUE'	System	07 Apr 2021 20:13:56
	Tammy Kohn (b) (4)	07 Apr 2021 20:13:46
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:28
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:29
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:31
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered '11 Sep 2020'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:34
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Apr 2021 20:14:01
User entered '05:00' reason for change: Data Entry Error	Tammy Kohn (b) (4)	07 Apr 2021 20:14:01
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Apr 2021 20:13:46
User entered empty.	System	07 Apr 2021 20:13:46
	Tammy Kohn (b) (4)	07 Apr 2021 20:13:46
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
User entered '11 Sep 2020 05:00'	System	07 Apr 2021 20:14:01
User entered empty.	System	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered '20 Sep 2020'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Apr 2021 20:14:01
User entered '17:30' reason for change: Data Entry Error	Tammy Kohn (b) (4)	07 Apr 2021 20:14:01
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Apr 2021 20:13:46
User entered empty.	System	07 Apr 2021 20:13:46
	Tammy Kohn (b) (4)	07 Apr 2021 20:13:46
	(b) (4)	

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
User entered '20 Sep 2020 17:30'	System	07 Apr 2021 20:14:01
User entered empty.	System	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:46
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:50
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:52
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:55
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:18:59
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:00
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:02
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:04
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:06
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:09
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:11
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:13
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered 'Related (RELATED)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:29
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered 'Related (RELATED)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:31
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered 'None (NONE)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:33
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered 'l'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:34
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:36
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:38
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:41
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:19:42
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
User entered '0'	System	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13
User entered '0'	System	07 Apr 2021 20:13:46

US3402316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:36:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:40:13

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:06
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
User closed query 'Per ETRTR: Please confirm whether medication has been dosed for COVID-19. Update ConMeds and AE CRF otherwise, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:15:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:59:54
Query 'Per ETRTR: Please confirm whether medication has been dosed for COVID-19. Update ConMeds and AE CRF otherwise, thanks.' answered with 'No Medication was given for covid' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	28 Oct 2020 13:45:50
User opened query 'Per ETRTR: Please confirm whether medication has been dosed for COVID-19. Update ConMeds and AE CRF otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:40:59
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:05

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:52:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:52:20
Data point term sent to Coder	System	10 Aug 2020 20:54:56
User entered 'WELLBUTRIN xl'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'ANXIETY AND DEPRESSION'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '300'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:53
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (MAR 2020). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 18:27:13
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (MAR 2020). Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'CORRECTED IN MEDICAL HISTORY TO MATCH SHOW MATCHING DATES.' (Site from DM).	Traci Hull (b) (4)	23 Sep 2020 18:34:44
	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (MAR 2020). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:49:48
User closed 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).	(b) (4), (b) (6)	14 Aug 2020 13:32:06
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.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	10 Aug 2020 20:56:40
	(b) (4)	
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	10 Aug 2020 20:54:55
User entered 'UN Dec 2019'	Traci Hull (b) (4)	10 Aug 2020 20:54:55
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 20:54:55

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM HYDROBROMIDE, PRODUCTSYNONYM: CELEXA [CITALOPRAM HYDROBROMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 00:01:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 00:01:00
Data point term sent to Coder	System	08 Sep 2020 17:19:06
Datapoint queued for coding (5050282).	System	08 Sep 2020 17:18:36
Data point term sent to Coder	System	10 Aug 2020 20:56:02
User entered 'celexa'	Traci Hull (b) (4)	10 Aug 2020 20:55:56
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'ANXIETY AND DEPRESSION'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '5'	Traci Hull (b) (4)	10 Aug 2020 20:55:56
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 20:56:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 20:56:31
User entered 'once daily (QD)' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:56:31
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 20:55:56
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 20:56:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 20:56:31
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Traci Hull (b) (4)	10 Aug 2020 20:56:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 20:55:56
User entered empty.	Traci Hull (b) (4)	10 Aug 2020 20:55:56
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User closed 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).	(b) (4), (b) (6)	14 Aug 2020 13:32:10
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.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	10 Aug 2020 20:56:16
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).	(b) (4)	
User entered 'UN Jul 2020'	System	10 Aug 2020 20:55:56
	Traci Hull (b) (4)	10 Aug 2020 20:55:56
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 20:56:31
User entered empty.	System	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 20:56:31
User entered empty.	System	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 20:56:31
User entered empty.	System	10 Aug 2020 20:55:56

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP)' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:57:17
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP)' answered with 'CORRECT AS IS.' (Site from DM).	Traci Hull (b) (4)	15 Oct 2020 16:12:08
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP)' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:44:32
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.	Coder Import (b) (4)	16 Sep 2020 18:14:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 18:14:46
Data point term sent to Coder	System	16 Sep 2020 18:13:43
User entered 'INFLUENZA VACCINE'	Traci Hull (b) (4)	16 Sep 2020 18:13:32

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'Yes (Y)'	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'FLU PREVENTION'	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '0.5'	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'mL (mL)'	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'once (ONCE)'	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'Intramuscular (INTRAMUSCULAR)'	Traci Hull (b) (4)	16 Sep 2020 18:13:32

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '10 Sep 2020'	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '0'	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'No (N)'	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '10 Sep 2020'	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'No (N)'	Traci Hull (b) (4)	16 Sep 2020 18:13:32
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User entered empty.	System	16 Sep 2020 18:13:32

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User entered empty.	System	16 Sep 2020 18:13:32

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:39
User entered empty.	System	16 Sep 2020 18:13:32

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN, PRODUCTSYNONYM: CIPRO [CIPROFLOXACIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 18:15:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Sep 2020 18:15:49
Data point term sent to Coder	System	16 Sep 2020 18:14:45
User entered 'CIPRO'	Traci Hull (b) (4)	16 Sep 2020 18:14:30

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'No (N)'	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'URINARY TRACT INFECTION'	Traci Hull (b) (4)	16 Sep 2020 18:14:30

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '250'	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'mg (mg)'	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'twice daily (BID)'	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '10 Sep 2020'	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '0'	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'No (N)'	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '16 Sep 2020'	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'No (N)'	Traci Hull (b) (4)	16 Sep 2020 18:14:30
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User entered '2'	System	16 Sep 2020 18:14:30

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User entered '1'	System	16 Sep 2020 18:14:30

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:36:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:59:45
User entered '804 (804)'	System	16 Sep 2020 18:14:30

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
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.	(b) (4) Coder Import (b) (4)	07 Nov 2020 14:19:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 14:19:31
Data point term sent to Coder	System	07 Nov 2020 14:18:46
Coding entries removed.	Jennifer Molstead (b) (4)	07 Nov 2020 14:18:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
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)	15 Oct 2020 16:15:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 16:15:27
Data point term sent to Coder	System	15 Oct 2020 16:14:37
User entered 'acetaminophen'	Traci Hull (b) (4)	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:42:12
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:52:17
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:52:13
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Updated' (Site from DM).	Jennifer Molstead (b) (4)	07 Nov 2020 14:18:35
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'Anterior cruciate ligament' (Site from DM).	Jennifer Molstead (b) (4)	07 Nov 2020 14:18:29
DataPoint Un-verified.	Jennifer Molstead (b) (4)	07 Nov 2020 14:18:12
User entered 'Pain at injection site' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 14:18:12
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:14:49

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:12:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'PAIN'	Traci Hull (b) (4)	15 Oct 2020 16:13:48
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '500'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'as needed (PRN)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:15:44
User closed query 'Per source start date was 12-SEP-20' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 03:15:42
Query 'Per source start date was 12-SEP-20' answered with 'Updated' (Site from CRA).	Jennifer Molstead (b) (4)	07 Nov 2020 14:18:45
DataPoint Un-verified.	(b) (4)	
	Jennifer Molstead (b) (4)	07 Nov 2020 14:18:12
User entered '12 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Jennifer Molstead (b) (4)	07 Nov 2020 14:18:12
User opened query 'Per source start date was 12-SEP-20' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 22:33:17
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '12 Oct 2020'	Traci Hull (b) (4)	15 Oct 2020 16:13:48
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered '0'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:02:02
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 15:42:23
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'NOT AN AE AS THIS IS WITHIN 7 DAYS OF LAST INJECTION' (Site from DM).	Tammy Kohn (b) (4)	04 Dec 2020 14:18:31
	(b) (4)	
DataPoint Un-verified.	Tammy Kohn (b) (4)	04 Dec 2020 14:18:27
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	04 Dec 2020 14:18:27
	(b) (4)	
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:51:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:30:56
User entered 'No (N)'	Traci Hull (b) (4)	15 Oct 2020 16:13:48
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:36:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:13:48

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:02:14
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 18:55:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 18:55:39
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 18:55:28
User entered 'NuvaRing'	Jennifer Molstead (b) (4)	10 Nov 2020 18:55:15
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:02:16
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	10 Nov 2020 18:55:15
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:02:17
User entered 'Birth Control'	Jennifer Molstead (b) (4)	10 Nov 2020 18:55:15
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:02:21
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.015/0.12).' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 12:18:24
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.015/0.12).' answered with '11.7 mg etonogestrel and 2.7 mg ethinyl estradiol MONTHLY. DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	05 Feb 2021 19:53:54
	(b) (4)	
User entered '11.7/2.7' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Feb 2021 19:53:34
	(b) (4)	
User entered '11.7' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Feb 2021 19:53:13
	(b) (4)	
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.015/0.12).' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 08:25:15
User entered '0.120' reason for change: Data Entry Error	Tammy Kohn (b) (4)	04 Dec 2020 14:20:02
	(b) (4)	
User entered '120'	Jennifer Molstead (b) (4)	10 Nov 2020 18:55:15
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 18:02:23
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 15:42:57
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	04 Dec 2020 14:20:12
User entered 'mg (mg)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	04 Dec 2020 14:20:02
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:51:33
User entered 'IU (IU)'	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 18:55:15

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:02:25
User entered empty.	Jennifer Molstead (b) (4)	10 Nov 2020 18:55:15
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:04:15
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).	(b) (4), (b) (6)	13 Jan 2021 15:18:16
User entered 'every month (QM)' reason for change:	Tammy Kohn (b) (4)	12 Jan 2021 17:14:54
Data Entry Error	(b) (4)	
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4)	12 Jan 2021 17:13:44
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Tammy Kohn (b) (4)	12 Jan 2021 17:13:35
Data Entry Error	(b) (4)	
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)	12 Jan 2021 16:59:07
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	10 Nov 2020 18:55:15
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:04:17
User entered empty.	Jennifer Molstead (b) (4)	10 Nov 2020 18:55:15
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:04:20
User entered 'Vaginal (VAGINAL)'	Jennifer Molstead (b) (4)	10 Nov 2020 18:55:15
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:04:22
User entered empty.	Jennifer Molstead (b) (4)	10 Nov 2020 18:55:15
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:04:24
User entered 'un UNK 2018'	Jennifer Molstead (b) (4)	10 Nov 2020 18:55:15
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:04:26
User entered '0'	Jennifer Molstead (b) (4)	10 Nov 2020 18:55:15
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Feb 2021 18:04:28
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	10 Nov 2020 18:55:15
	(b) (4)	

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 18:04:33
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 18:55:15

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 18:04:35
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 18:55:15

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Jan 2021 17:14:54
User entered empty.	System	12 Jan 2021 17:13:35
User entered '1'	System	10 Nov 2020 18:55:15

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Jan 2021 17:14:54
User entered empty.	System	12 Jan 2021 17:13:35
User entered '1'	System	10 Nov 2020 18:55:15

US3402316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:36:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	12 Jan 2021 17:14:54
User entered empty.	System	12 Jan 2021 17:13:35
User entered '804 (804)'	System	10 Nov 2020 18:55:15

US3402316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:36:03

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:37:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:37:47
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 20:56:56

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered		
'USA-US059-2020-MRNA-1273-P301000008'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 20:28:02
Un-reviewed for Safety.	System	28 Oct 2020 15:21:01
User entered 'No (N)'	System	28 Oct 2020 15:21:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
Un-reviewed for Safety.	System	24 Oct 2020 00:21:52
User entered 'Yes (Y)'	System	24 Oct 2020 00:21:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 20:28:02
Un-reviewed for Safety.	System	28 Oct 2020 15:21:01
User entered 'No (N)'	System	28 Oct 2020 15:21:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
Un-reviewed for Safety.	System	24 Oct 2020 00:21:52
User entered 'Yes (Y)'	System	24 Oct 2020 00:21:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Frank'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Eder'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered '1290 Upper Front Street'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Binghamton'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'NY'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered '13901'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
User entered 'US'	System	19 Oct 2020 17:30:08

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Nov 2020 22:50:18
User entered '3'	System	28 Oct 2020 20:28:18
User entered '2'	System	26 Oct 2020 19:00:32
User entered '1'	System	19 Oct 2020 17:30:08

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered		
'USA-US059-2020-MRNA-1273-P301000008'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 20:28:02
Un-reviewed for Safety.	System	28 Oct 2020 15:21:01
User entered 'No (N)'	System	28 Oct 2020 15:21:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
Un-reviewed for Safety.	System	24 Oct 2020 00:21:52
User entered 'Yes (Y)'	System	24 Oct 2020 00:21:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 20:28:02
Un-reviewed for Safety.	System	28 Oct 2020 15:21:01
User entered 'No (N)'	System	28 Oct 2020 15:21:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
Un-reviewed for Safety.	System	24 Oct 2020 00:21:52
User entered 'Yes (Y)'	System	24 Oct 2020 00:21:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Frank'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Eder'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered '1290 Upper Front Street'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Binghamton'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'NY'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered '13901'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
User entered 'US'	System	19 Oct 2020 17:30:08

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Nov 2020 22:50:18
User entered '3'	System	28 Oct 2020 20:28:18
User entered '2'	System	26 Oct 2020 19:00:32
User entered '1'	System	19 Oct 2020 17:30:08

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:36:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:01
User entered '19/Oct/2020 17:30'	System	19 Oct 2020 17:30:08

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:36:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
User entered 'I'	(b) (4), (b) (6)	19 Oct 2020 17:30:08

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered		
'USA-US059-2020-MRNA-1273-P301000008'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 20:28:02
Un-reviewed for Safety.	System	28 Oct 2020 15:21:01
User entered 'No (N)'	System	28 Oct 2020 15:21:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
Un-reviewed for Safety.	System	24 Oct 2020 00:21:52
User entered 'Yes (Y)'	System	24 Oct 2020 00:21:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 20:28:02
Un-reviewed for Safety.	System	28 Oct 2020 15:21:01
User entered 'No (N)'	System	28 Oct 2020 15:21:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
Un-reviewed for Safety.	System	24 Oct 2020 00:21:52
User entered 'Yes (Y)'	System	24 Oct 2020 00:21:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Frank'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Eder'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered '1290 Upper Front Street'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Binghamton'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'NY'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered '13901'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
User entered 'US'	System	19 Oct 2020 17:30:08

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Nov 2020 22:50:18
User entered '3'	System	28 Oct 2020 20:28:18
User entered '2'	System	26 Oct 2020 19:00:32
User entered '1'	System	19 Oct 2020 17:30:08

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:36:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:01
User entered '26/Oct/2020 19:00'	System	26 Oct 2020 19:00:32

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:36:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 20:28:02
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 19:00:32

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered		
'USA-US059-2020-MRNA-1273-P301000008'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 20:28:02
Un-reviewed for Safety.	System	28 Oct 2020 15:21:01
User entered 'No (N)'	System	28 Oct 2020 15:21:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
Un-reviewed for Safety.	System	24 Oct 2020 00:21:52
User entered 'Yes (Y)'	System	24 Oct 2020 00:21:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 20:28:02
Un-reviewed for Safety.	System	28 Oct 2020 15:21:01
User entered 'No (N)'	System	28 Oct 2020 15:21:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
Un-reviewed for Safety.	System	24 Oct 2020 00:21:52
User entered 'Yes (Y)'	System	24 Oct 2020 00:21:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Frank'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Eder'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered '1290 Upper Front Street'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Binghamton'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'NY'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered '13901'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
User entered 'US'	System	19 Oct 2020 17:30:08

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Nov 2020 22:50:18
User entered '3'	System	28 Oct 2020 20:28:18
User entered '2'	System	26 Oct 2020 19:00:32
User entered '1'	System	19 Oct 2020 17:30:08

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:36:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:01
User entered '28/Oct/2020 16:28'	System	28 Oct 2020 20:28:18

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:36:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 22:50:07
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 20:28:18

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered		
'USA-US059-2020-MRNA-1273-P301000008'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 20:28:02
Un-reviewed for Safety.	System	28 Oct 2020 15:21:01
User entered 'No (N)'	System	28 Oct 2020 15:21:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
Un-reviewed for Safety.	System	24 Oct 2020 00:21:52
User entered 'Yes (Y)'	System	24 Oct 2020 00:21:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 20:28:02
Un-reviewed for Safety.	System	28 Oct 2020 15:21:01
User entered 'No (N)'	System	28 Oct 2020 15:21:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
Un-reviewed for Safety.	System	24 Oct 2020 00:21:52
User entered 'Yes (Y)'	System	24 Oct 2020 00:21:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'No (N)'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Frank'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Eder'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered '1290 Upper Front Street'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'Binghamton'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered 'NY'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 17:30:02
User entered '13901'	System	19 Oct 2020 17:29:40

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 19:00:15
User entered 'US'	System	19 Oct 2020 17:30:08

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Nov 2020 22:50:18
User entered '3'	System	28 Oct 2020 20:28:18
User entered '2'	System	26 Oct 2020 19:00:32
User entered '1'	System	19 Oct 2020 17:30:08

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:36:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:20:01
User entered '03/Nov/2020 17:50'	System	03 Nov 2020 22:50:18

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:36:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:20:01
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 22:50:18

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered		
'USA-US059-2020-MRNA-1273-P301000011'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 19:30:09
User closed query 'Please update to "No".' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 19:30:08
Query 'Please update to "No".' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	07 Nov 2020 14:46:04
Un-reviewed for Safety.	(b) (4)	
	Jennifer Molstead (b) (4)	07 Nov 2020 14:45:54
DataPoint Un-verified.	(b) (4)	
	Jennifer Molstead (b) (4)	07 Nov 2020 14:45:54
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:12
User opened query 'Please update to "No".' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 23:16:09
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'Yes (Y)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'No (N)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'No (N)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'No (N)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'No (N)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'No (N)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'Yes (Y)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'Frank'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'Eder'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered '1290 Upper Front Street'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'Binghamton'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'NY'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered '13901'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:12
User entered 'US'	System	26 Oct 2020 18:58:50

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Oct 2020 18:58:50

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered		
'USA-US059-2020-MRNA-1273-P301000011'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Nov 2020 19:30:09
User closed query 'Please update to "No".' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 19:30:08
Query 'Please update to "No".' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	07 Nov 2020 14:46:04
Un-reviewed for Safety.	(b) (4)	
	Jennifer Molstead (b) (4)	07 Nov 2020 14:45:54
DataPoint Un-verified.	(b) (4)	
	Jennifer Molstead (b) (4)	07 Nov 2020 14:45:54
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 23:16:12
User opened query 'Please update to "No".' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 23:16:09
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'Yes (Y)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'No (N)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'No (N)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'No (N)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'No (N)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'No (N)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'Yes (Y)'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'Frank'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'Eder'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered '1290 Upper Front Street'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'Binghamton'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered 'NY'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 18:58:44
User entered '13901'	System	26 Oct 2020 18:58:10

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:12
User entered 'US'	System	26 Oct 2020 18:58:50

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:36:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Oct 2020 18:58:50

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:36:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 23:16:12
User entered '26/Oct/2020 18:58'	System	26 Oct 2020 18:58:50

US3402316

Folder: SAE USA-US059-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:36:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:09:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 23:16:12
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 18:58:50