

US3632107 (Prod: Grady Health System)

Generated By: KC Joubran

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US3632107

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 17:43:52

Generated On: 11 Aug 2021 22:54:03

Participant ID

US3632107

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

US3632107

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:43:58

Generated On: 11 Aug 2021 22:54:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3632107

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	CREOLE
Unknown	False
Not reported	False

US3632107

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify _____	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number _____	
Enrollment Trigger	1

US3632107

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3632107

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 17:43:58

Generated On: 11 Aug 2021 22:54:03

Were any significant conditions reported?

Yes ☒

No ☐

US3632107

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Feb 2021 17:43:58

Generated On: 11 Aug 2021 22:54:03

Condition	HERNIA (LEFT INGUINAL, SURGERY)
Start date (dd MMM yyyy)	1 UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	1 UNK 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

US3632107

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 17:43:58

Generated On: 11 Aug 2021 22:54:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	9:40 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 9:40
Height (<i>xxx.x</i>)	66 in
Weight (<i>xxx.x</i>)	182 lb
BMI (<i>xxx.x</i>)	29.43699 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3632107

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:43:58

Generated On: 11 Aug 2021 22:54:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3632107

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 17:43:58

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 17:43:58

Generated On: 11 Aug 2021 22:54:03

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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3632107

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3632107

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

What was the date of randomization? (dd MMM yyyy) 24 SEP 2020

What was the participant's randomization number? 115475

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 ☒

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

Height	ND - Not Done
Weight	ND - Not Done

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

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)	24 SEP 2020
Time of assessment (00:00-23:59)	9:40 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 9:40
Temperature (xxx.x)	97 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

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)	24 SEP 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 11:55
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3632107

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3632107

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:43:58

Generated On: 11 Aug 2021 22:54:03

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 11:18 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 11:18

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

US3632107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 17:43:58

Generated On: 11 Aug 2021 22:54:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

10:18 (24 HR)

Collection date and time (derived)

24 SEP 2020 10:18

US3632107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 17:43:58

Generated On: 11 Aug 2021 22:54:03

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:22	24 SEP 2020 10:22
Nasopharyngeal Swab 2	No		

US3632107

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:58

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 11:46

PC Open Date & Time

24 SEP 2020 11:38

PC Close Date & Time

24 SEP 2020 14:08

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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	24 SEP 2020 23:14
PC Open Date & Time	24 SEP 2020 15:03
PC Close Date & Time	25 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

97.0 °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

25 SEP 2020 23:40

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 22:32

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

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

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

PC Time Stamp	29 SEP 2020 10:50
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

96.0 °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

30 SEP 2020 09:39

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

96.0 °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

30 SEP 2020 12:54

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 11:47

PC Open Date & Time

24 SEP 2020 11:38

PC Close Date & Time

24 SEP 2020 14:08

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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

24 SEP 2020 23:14

PC Open Date & Time

24 SEP 2020 15:03

PC Close Date & Time

25 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

25 SEP 2020 23:41

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

27 SEP 2020 22:33

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

29 SEP 2020 10:50

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

30 SEP 2020 09:39

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

30 SEP 2020 12:54

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 11:47
PC Open Date & Time	24 SEP 2020 11:38
PC Close Date & Time	24 SEP 2020 14:08

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 23:15
PC Open Date & Time	24 SEP 2020 15:03
PC Close Date & Time	25 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

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 ☒

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 23:42
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

46 of 3056

EAB) (1725)

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 22:33
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

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
EAB) (1725)

48 of 3056

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 10:51
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

50 of 3056

EAB) (1725)

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 09:40
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

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 ☒

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 12:55
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:54:03

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 01 OCT 2020 12:19

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 OCT 2020 12:19

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

DAY 9

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

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

DAY 10

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

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:54:03

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	01 OCT 2020 12:19
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3632107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632107

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632107

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632107

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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	VISIT2

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

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)	20 OCT 2020
Time of assessment (00:00-23:59)	8:44 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 8:44
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

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)	20 OCT 2020
Time of assessment (00:00-23:59)	11:29 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 11:29
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3632107

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3632107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

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) 20 OCT 2020

What was the treatment time? (00:00-23:59) 10:57 (24 HR)

Treatment Date and Time (derived) 20 OCT 2020 10:57

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

US3632107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 OCT 2020

Collection time (00:00-23:59)

9:07 (24 HR)

Collection date and time (derived)

20 OCT 2020 9:07

US3632107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

Collection date (dd MMM yyyy)			20 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	9:10	20 OCT 2020 9:10
Nasopharyngeal Swab 2	No		

US3632107

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

97.2 °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

20 OCT 2020 11:24

PC Open Date & Time

20 OCT 2020 11:17

PC Close Date & Time

20 OCT 2020 13:47

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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 96.7 °F

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

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

PC Time Stamp	20 OCT 2020 23:14
PC Open Date & Time	20 OCT 2020 14:42
PC Close Date & Time	21 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 09:41

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 22:47

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

24 OCT 2020 02:46

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

97.5 °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

24 OCT 2020 20:51

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 21:06

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

98.5 °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

26 OCT 2020 21:14

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 11:24

PC Open Date & Time

20 OCT 2020 11:17

PC Close Date & Time

20 OCT 2020 13:47

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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

20 OCT 2020 23:14

PC Open Date & Time

20 OCT 2020 14:42

PC Close Date & Time

21 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

22 OCT 2020 09:42

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

22 OCT 2020 22:48

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

24 OCT 2020 02:46

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

24 OCT 2020 20:51

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

25 OCT 2020 21:06

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

26 OCT 2020 21:14

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

No ☒

Yes ☐

PC Time stamp	20 OCT 2020 11:25
PC Open Date & Time	20 OCT 2020 11:17
PC Close Date & Time	20 OCT 2020 13:47

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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

No ☒

Yes ☐

PC Time stamp	20 OCT 2020 23:15
PC Open Date & Time	20 OCT 2020 14:42
PC Close Date & Time	21 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

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 ☒

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 09:42
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

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 ☒

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 22:48
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

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 ☒

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 02:46
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

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 ☒

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 20:52
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

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 ☒

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 21:06
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

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 3056

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 21:14
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3632107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632107

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3632107

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632107

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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	VISIT3

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

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) _____

US3632107

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

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.

US3632107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 NOV 2020

Collection time (00:00-23:59)

08:46 (24 HR)

Collection date and time (derived)

17 NOV 2020 08:46

US3632107

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:59

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	True
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input 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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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	23 NOV 2020 15:14:18
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	True
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 NOV 2020 10:26:57
Patient Cloud Open Date & Time	28 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	120 of 3056

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	05 DEC 2020 11:05:47
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 15:45:28
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 16:55:04

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 09:40:12
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

Date and time of submission

02 JAN 2021 00:23:53

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 17:18:17
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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	17 JAN 2021 22:54:06
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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	27 JAN 2021 11:42:04
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

01 FEB 2021 12:08:55

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

10 FEB 2021 08:35:11

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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	13 FEB 2021 09:42:29
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

22 FEB 2021 22:18:15

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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	02 MAR 2021 01:17:05
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

Date and time of submission

06 MAR 2021 12:22:12

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

Date and time of submission

13 MAR 2021 11:54:26

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

24 MAR 2021 10:47:38

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

31 MAR 2021 10:50:15

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

05 APR 2021 15:44:36

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

13 APR 2021 01:00:12

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

19 APR 2021 10:03:36

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

24 APR 2021 11:07:41

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	True
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	03 MAY 2021 10:15:01
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐
Yes ☐

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

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

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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°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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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°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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐
Yes ☐

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

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

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

Patient Cloud Open Date & Time	02 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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°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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐
Yes ☐

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

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

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐
Yes ☐

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

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

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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°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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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°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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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°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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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°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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐
Yes ☐

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

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

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 <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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐
Yes ☐

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

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

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐
Yes ☐

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

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

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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="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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐
Yes ☐

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

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

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3632107

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:54:03

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		02 MAR 2021 01:17:17

US3632107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632107

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632107

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632107

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632107

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 15:42:28

Generated On: 11 Aug 2021 22:54:03

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

Visit date (dd MMM yyyy)	21 APR 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
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US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 15:42:28

Generated On: 11 Aug 2021 22:54:03

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) _____

US3632107

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 15:42:28

Generated On: 11 Aug 2021 22:54:03

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.

US3632107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 15:42:28

Generated On: 11 Aug 2021 22:54:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 APR 2021

Collection time (00:00-23:59)

10:25 (24 HR)

Collection date and time (derived)

21 APR 2021 10:25

US3632107

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:42:28

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 22 Feb 2021 17:43:53

Generated On: 11 Aug 2021 22:54:03

Date of Contact	23 NOV 2020
Time of Contact	12:00
Date and Time of Contact (derived)	23 NOV 2020 12:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

326 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

327 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

330 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

331 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

334 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

335 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

338 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

342 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

347 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

350 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 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 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

351 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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)

354 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 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 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

355 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

359 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

363 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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)

366 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

367 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.3 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)

370 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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)

374 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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)

375 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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	1 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	96.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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)

379 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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	2 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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)

383 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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	3 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

386 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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)

387 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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	4 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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)

390 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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)

391 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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	5 DEC 2020	
Assessment Not Done	False	
O2 Saturation	89 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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	6 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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)

398 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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	7 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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)

402 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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)

403 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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	8 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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)

406 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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)

407 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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	9 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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	10 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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)

414 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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)

415 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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)

419 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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"/>

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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)

422 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

	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)

423 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 22 Feb 2021 17:43:52

Generated On: 11 Aug 2021 22:54:03

Date of Visit	24 NOV 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	24 NOV 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

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

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 05 DEC 2020

End Date 05 DEC 2020

Oxygen Saturation 89 %

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)

426 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

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)

427 of 3056

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 22 Feb 2021 17:43:53

Generated On: 11 Aug 2021 22:54:03

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 22 Feb 2021 17:43:54

Generated On: 11 Aug 2021 22:54:03

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	Yes	28 NOV 2020
Day 7	Yes	30 NOV 2020
Day 9	Yes	2 DEC 2020
Day 14	Yes	7 DEC 2020
Day 21	Yes	14 DEC 2020
Day 28	Yes	21 DEC 2020

US3632107

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 17:43:54

Generated On: 11 Aug 2021 22:54:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 NOV 2020
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	24 NOV 2020 10:19
Height (xxx.x)	66 in
Weight (xxx.x)	186.4 lb
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:43:54

Generated On: 11 Aug 2021 22:54:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 NOV 2020

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

US3632107

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 22 Feb 2021 17:43:54

Generated On: 11 Aug 2021 22:54:03

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

24 NOV 2020

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:43:52

Generated On: 11 Aug 2021 22:54:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 17:43:52

Generated On: 11 Aug 2021 22:54:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 DEC 2020
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	21 DEC 2020 10:20
Height (xxx.x)	66 in
Weight (xxx.x)	189.6 lb
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:43:52

Generated On: 11 Aug 2021 22:54:03

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.

US3632107

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 22 Feb 2021 17:43:52

Generated On: 11 Aug 2021 22:54:03

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 DEC 2020

US3632107

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

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

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3632107

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 01:36:21

Generated On: 11 Aug 2021 22:54:03

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3632107

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Height	66 in
Weight	ND - Not Done
BMI (xxx.x)	

US3632107

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Height	66 in
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 10:10
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3632107

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Height	66 in
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 11:42
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3632107

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

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3632107

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

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

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

Treatment Date and Time (derived) 14 JAN 2021 11:11

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

US3632107

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

09:50 (24 HR)

Collection date and time (derived)

14 JAN 2021 09:50

US3632107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	09:52
Collection Date and Time (derived)	14 JAN 2021 09:52

US3632107

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

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632107

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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	OLD29

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

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 (<i>dd MMM yyyy</i>)	8 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	08:44 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 08:44
Temperature (<i>xxx.x</i>)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	59 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 17:43:55

Generated On: 11 Aug 2021 22:54:03

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 FEB 2021
Time of assessment (00:00-23:59)	10:57 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 10:57
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3632107

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 17:43:54

Generated On: 11 Aug 2021 22:54:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 FEB 2021

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

US3632107

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 17:43:54

Generated On: 11 Aug 2021 22:54:03

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 8 FEB 2021

What was the treatment time? (00:00-23:59) 10:26 (24 HR)

Treatment Date and Time (derived) 8 FEB 2021 10:26

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

US3632107

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 17:43:54

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3632107

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3632107

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

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) _____

US3632107

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

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.

US3632107

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 MAR 2021

Collection time (00:00-23:59)

10:33 (24 HR)

Collection date and time (derived)

11 MAR 2021 10:33

US3632107

Folder: Unscheduled 23 Nov 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Visit Date	23 NOV 2020
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

US3632107

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 17:43:52

Generated On: 11 Aug 2021 22:54:03

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:19:04

Generated On: 11 Aug 2021 22:54:03

AEID	USA-US120-2020-MRNA-1273-P30 1000007
Adverse event	SYMPTOMATIC 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)	17 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 DEC 2020
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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

465 of 3056

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:19:04

Generated On: 11 Aug 2021 22:54:03

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT DEVELOPED SYMPTOMS ON 11/17/20. HE TESTED POSITIVE OUTSIDE OF THE STUDY AND THEN PRESENTED FOR ILLNESS VISIT ON 11/24/20.
Serious Adverse Event Derived (CSA Programming Field Only)	0

PRODUCTION RELEASE (v12.003
EAB) (1725)

466 of 3056

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:19:04

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:19:04

Generated On: 11 Aug 2021 22:54:03

AEID

Adverse event

RECTAL BLEEDING

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)

23 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

EAB) (1725)

468 of 3056

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:19:04

Generated On: 11 Aug 2021 22:54:03

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒

Related ☐

Not Applicable ☐

Relationship to Study Procedure Not Related ☒

Related ☐

Not Applicable ☐

Action taken with investigational product None ☐

Dose Delayed ☐

Investigational Product ☐

Withdrawn ☐

Not Applicable ☒

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal ☐

Not Recovered/Not Resolved ☐

Recovered/Resolved ☒

Recovered/Resolved with ☐

Sequelae ☐

Recovering/Resolving ☐

Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

PARTICIPANT WAS TAKING NSAIDS WHEN HIS SYMPTOMS OF COVID STARTED AND NOTICED THE IMMEDIATE ONSET OF RECTAL BLEEDING. HE HAS SINCE STOPPED ALL MEDICATIONS AND THE RECTAL BLEEDING HAS PERSISTED.

PRODUCTION RELEASE (v12.003

469 of 3056

EAB) (1725)

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:19:04

Generated On: 11 Aug 2021 22:54:03

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)	

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:19:04

Generated On: 11 Aug 2021 22:54:03

AEID

Adverse event

GENERAL JOINT ACHES

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)

27 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)

1 OCT 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

471 of 3056

EAB) (1725)

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:19:04

Generated On: 11 Aug 2021 22:54:03

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 checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 17:43:52

Generated On: 11 Aug 2021 22:54:03

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

Yes ☒

No ☐

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

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication FISH OIL (OMEGA-3)

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration UNKNOWN

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

474 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	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)	1 UNK 2018	
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"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration UNKNOWN

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

476 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	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)	1 UNK 2018	
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"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration UNKNOWN

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

478 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	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)	1 UNK 2018	
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"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication VITAMIN B12

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration UNKNOWN

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

480 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	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)	1 UNK 2018	
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"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication GLUCOSAMINE

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration UNKNOWN

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

482 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	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)	1 UNK 2018	
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"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration UNKNOWN

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

484 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	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)	1 UNK 2018	
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"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication IRON

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration UNKNOWN

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

486 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	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)	1 UNK	2018
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"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication MUSCLE ACHES

Dose per administration 200

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)

488 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	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)		28 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) 28 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication MUSCLE ACHES

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

490 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	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)	28 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) 28 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication COVID 19 SYMPTOMS

Dose per administration 81

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

492 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	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)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 NOV 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"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication	DAYQUIL (ACETAMINOPHEN 325 MG/PHENYLEPHRINE 5MG/DEXTROMETHORPHAN HBR 10MG)
--------------------	---

Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
-------------	--

Indication	COVID 19 SYMPTOMS
------------	-------------------

Dose per administration	325/5/10
-------------------------	----------

Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
-----------	---

If dose unit is Other, specify

Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
-----------	---

If frequency is Other, specify

Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/>
-------------------------	---

PRODUCTION RELEASE (v12.003
EAB) (1725)

494 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 NOV 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"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication NYQUIL (ACETAMINOPHEN 325
MG/DEXFROMETHORPHAN
HBR 10MG/DOXYLAMINE
SUCCINATE 6.25MG)

Prophylaxis Yes ☐
No ☒

Indication COVID 19 SYMPTOMS

Dose per administration 325/10/6.25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

496 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication COVID 19 SYMPTOMS

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

498 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	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)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 NOV 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"/>

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

Name of Medication HALLS COUGH DROPS
(MENTHOL 7.5 MG)

Prophylaxis Yes ☐
No ☒

Indication COVID 19 SYMPTOMS

Dose per administration 7.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

6 TIME PER DAY

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

500 of 3056

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3632107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 17:43:52

Generated On: 11 Aug 2021 22:54:03

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3632107

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:54:03

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

US3632107

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:54:03

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 ☐

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

SAEID	USA-US120-2020-MRNA-1273-P301000007
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

SAEID	USA-US120-2020-MRNA-1273-P301000007
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/DEC/2020 02:41
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

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

SAEID	USA-US120-2020-MRNA-1273-P301000007
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/FEB/2021 17:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 01:16:31

Generated On: 11 Aug 2021 22:54:03

SAEID	USA-US120-2020-MRNA-1273-P301000007
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	COLLEEN
Investigator's Last Name	KELLEY
Site Address: Street	
Site Address: City	
Site Address: State	GA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/MAR/2021 16:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3632107 (Prod: Grady Health System)

US3632107

Form: Participant Creation

Generated On: 11 Aug 2021 22:54:03

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 16:40:21
User entered 'US3632107'	RWS_ENDPOINT	24 Sep 2020 13:19:22
	ENDPOINT (b) (4)	

US3632107

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Isaac Perez (b) (4)	24 Sep 2020 14:51:23

US3632107

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '24 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 13:19:24

US3632107

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Clinic (Clinic)'	Isaac Perez (b) (4)	24 Sep 2020 14:51:23

US3632107

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered 'SCRN'	System	24 Sep 2020 14:51:23

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered (b) (6) 1974'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 13:19:25

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '46'	Isaac Perez (b) (4)	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered 'YEARS'	System	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered '46'	System	24 Sep 2020 14:53:46

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Male (M)'	Isaac Perez (b) (4)	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Isaac Perez (b) (4)	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'I'	Isaac Perez (b) (4)	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Creole'	Isaac Perez (b) (4)	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:54:03

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	24 Sep 2020 14:53:30

US3632107

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:03

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '24 Sep 2020'	Isaac Perez (b) (4)	24 Sep 2020 14:53:46

US3632107

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered 'Sep 2020'	System	24 Sep 2020 14:53:46

US3632107

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered '2020'	System	24 Sep 2020 14:53:46

US3632107

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Amendment 3 (3)'	Isaac Perez (b) (4)	24 Sep 2020 14:53:46

US3632107

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	24 Sep 2020 14:53:46

US3632107

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:03

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	24 Sep 2020 14:53:46

US3632107

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	24 Sep 2020 14:53:46

US3632107

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	24 Sep 2020 14:53:46

US3632107

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 13:19:24

US3632107

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:54:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered 'I'	System	24 Sep 2020 14:53:51

US3632107

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	24 Sep 2020 14:53:51

US3632107

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:54:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:21:53

US3632107

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 17:55:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 17:55:52
Data point term sent to Coder	System	25 Sep 2020 17:26:39
User entered 'Hernia (Left inguinal, surgery)'	(b) (4), (b) (6)	25 Sep 2020 17:26:31

US3632107

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '1 UNK 1980'	(b) (4), (b) (6)	25 Sep 2020 17:26:31

US3632107

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 17:26:31

US3632107

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:26:31

US3632107

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:03

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '1 UNK 1980'	(b) (4), (b) (6)	25 Sep 2020 17:26:31

US3632107

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 17:26:31

US3632107

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered 'Jan 1980'	System	25 Sep 2020 17:26:31

US3632107

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered '1980'	System	25 Sep 2020 17:26:31

US3632107

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered 'Jan 1980'	System	25 Sep 2020 17:26:31

US3632107

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered '1980'	System	25 Sep 2020 17:26:31

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '24 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '9:40'	(b) (4), (b) (6)	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered '24 Sep 2020 9:40'	System	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '66' in	(b) (4), (b) (6)	25 Sep 2020 17:23:11
DataPoint set to visible.	System	24 Sep 2020 14:53:51

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '182' lb	(b) (4), (b) (6)	25 Sep 2020 17:23:11
DataPoint set to visible.	System	24 Sep 2020 14:53:51

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered '29.43699'	System	25 Sep 2020 17:23:11
DataPoint set to visible.	System	24 Sep 2020 14:53:51

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered 'kg/m2'	System	25 Sep 2020 17:23:11
DataPoint set to visible.	System	24 Sep 2020 14:53:51

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered 'bpm'	System	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered 'breaths/min'	System	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered 'mmHg'	System	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User entered 'mmHg'	System	25 Sep 2020 17:23:11

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13

US3632107

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13

US3632107

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:20:50

US3632107

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '24 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:20:50

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

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)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

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)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

[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)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

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)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

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)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

[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)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

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)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

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)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

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)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

[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)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'I'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

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)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:54:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:32:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:21:15

US3632107

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:27:02

US3632107

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:27:02

US3632107

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:27:02

US3632107

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'VISIT1'	System	25 Sep 2020 17:27:02

US3632107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '24 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 14:04:26

US3632107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:03

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '115475'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 14:04:26

US3632107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:03

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 14:04:26

US3632107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:03

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)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	Isaac Perez (b) (4)	24 Sep 2020 14:54:21

US3632107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:03

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)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	Isaac Perez (b) (4)	24 Sep 2020 14:54:21

US3632107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:03

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	Isaac Perez (b) (4)	24 Sep 2020 14:54:21

US3632107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:03

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	Isaac Perez (b) (4)	24 Sep 2020 14:54:21

US3632107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	Isaac Perez (b) (4)	24 Sep 2020 14:54:21

US3632107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:54:03

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	Isaac Perez (b) (4)	24 Sep 2020 14:54:21
DataPoint set to visible.	System	24 Sep 2020 14:53:46

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '24 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '9:40'	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered '24 Sep 2020 9:40'	System	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '97' F	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '54'	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'bpm'	System	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '10'	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'breaths/min'	System	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '120'	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'mmHg'	System	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '66'	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'mmHg'	System	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '11:55'	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered '24 Sep 2020 11:55'	System	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '96.8' F	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '51'	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'bpm'	System	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '12'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'breaths/min'	System	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '133'	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'mmHg'	System	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '65'	(b) (4), (b) (6)	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'mmHg'	System	25 Sep 2020 17:28:45

US3632107

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:51

US3632107

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:28:51

US3632107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Isaac Perez (b) (4)	24 Sep 2020 15:32:07

US3632107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Isaac Perez (b) (4)	24 Sep 2020 15:32:07

US3632107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

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)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Isaac Perez (b) (4)	24 Sep 2020 15:32:07

US3632107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 15:32:07

US3632107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '24 Sep 2020'	Isaac Perez (b) (4)	24 Sep 2020 15:32:07

US3632107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '11:18'	Isaac Perez (b) (4)	24 Sep 2020 15:32:07

US3632107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered '24 Sep 2020 11:18'	System	24 Sep 2020 15:32:07

US3632107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Left Arm (LEFT ARM)'	Isaac Perez (b) (4)	24 Sep 2020 15:32:07

US3632107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'ONCE'	System	24 Sep 2020 15:32:07

US3632107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 15:32:07

US3632107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:29:06

US3632107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '24 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:29:06

US3632107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '10:18'	(b) (4), (b) (6)	25 Sep 2020 17:29:06

US3632107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered '24 Sep 2020 10:18'	System	25 Sep 2020 17:29:06

US3632107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:54:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '24 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 17:29:17

US3632107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:54:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	25 Sep 2020 17:29:17

US3632107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:54:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:29:17

US3632107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:54:03

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '10:22'	(b) (4), (b) (6)	25 Sep 2020 17:29:17

US3632107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:54:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered '24 Sep 2020 10:22'	System	25 Sep 2020 17:29:17

US3632107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:54:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	25 Sep 2020 17:29:17

US3632107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:54:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:29:17

US3632107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:54:03

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:29:17

US3632107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:54:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered empty.	System	25 Sep 2020 17:29:17

US3632107

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:29:19

US3632107

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'I'	System	25 Sep 2020 17:29:19

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:45:11', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'b0b01d8d-4773-4032-b686-8ec10f088e09'	System	24 Sep 2020 15:46:34
User entered 'Yes (Y)'	System	24 Sep 2020 15:46:34

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:46:13', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'b0b01d8d-4773-4032-b686-8ec10f088e09'	System	24 Sep 2020 15:46:34
User entered '96.8'	System	24 Sep 2020 15:46:34

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:46:24', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'b0b01d8d-4773-4032-b686-8ec10f088e09'	System	24 Sep 2020 15:46:34
User entered 'No (N)'	System	24 Sep 2020 15:46:34

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:46:33', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'b0b01d8d-4773-4032-b686-8ec10f088e09'	System	24 Sep 2020 15:46:34
User entered '24 Sep 2020 11:46'	System	24 Sep 2020 15:46:34

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Sep 2020 11:38'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Sep 2020 14:08'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:13:54', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'cc6ded2a-87e0-4790-8869-17ff269215da'	System	25 Sep 2020 03:14:18
User entered 'Yes (Y)'	System	25 Sep 2020 03:14:18

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:05', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'cc6ded2a-87e0-4790-8869-17ff269215da'	System	25 Sep 2020 03:14:18
User entered '97.5'	System	25 Sep 2020 03:14:18

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:10', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'cc6ded2a-87e0-4790-8869-17ff269215da'	System	25 Sep 2020 03:14:18
User entered 'No (N)'	System	25 Sep 2020 03:14:18

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:15', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'cc6ded2a-87e0-4790-8869-17ff269215da'	System	25 Sep 2020 03:14:18
User entered '24 Sep 2020 23:14'	System	25 Sep 2020 03:14:18

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Sep 2020 15:03'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 2'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:40:20', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '3617449d-ffdc-4a0c-a440-9ee55a981455'	System	26 Sep 2020 03:45:04
User entered 'Yes (Y)'	System	26 Sep 2020 03:45:04

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:40:33', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '3617449d-ffdc-4a0c-a440-9ee55a981455'	System	26 Sep 2020 03:45:04
User entered '97.0'	System	26 Sep 2020 03:45:04

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:40:40', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '3617449d-ffdc-4a0c-a440-9ee55a981455'	System	26 Sep 2020 03:45:04
User entered 'No (N)'	System	26 Sep 2020 03:45:04

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:40:44', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '3617449d-ffdc-4a0c-a440-9ee55a981455'	System	26 Sep 2020 03:45:04
User entered '25 Sep 2020 23:40'	System	26 Sep 2020 03:45:04

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 3'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 4'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:32:29', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '661b451e-1eb6-4911-be9a-bc6e07e6e274'	System	28 Sep 2020 02:32:54
User entered 'Yes (Y)'	System	28 Sep 2020 02:32:54

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:32:43', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '661b451e-1eb6-4911-be9a-bc6e07e6e274' User entered '96.7'	System	28 Sep 2020 02:32:54
	System	28 Sep 2020 02:32:54

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:32:46', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '661b451e-1eb6-4911-be9a-bc6e07e6e274'	System	28 Sep 2020 02:32:54
User entered 'No (N)'	System	28 Sep 2020 02:32:54

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:32:51', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '661b451e-1eb6-4911-be9a-bc6e07e6e274'	System	28 Sep 2020 02:32:54
User entered '27 Sep 2020 22:32'	System	28 Sep 2020 02:32:54

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 5'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:49:49', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd08e19de-d956-466c-96c9-bd827aeebd17'	System	29 Sep 2020 14:50:20
User entered 'Yes (Y)'	System	29 Sep 2020 14:50:20

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:49:55', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd08e19de-d956-466c-96c9-bd827aeebd17'	System	29 Sep 2020 14:50:20
User entered '97.5'	System	29 Sep 2020 14:50:20

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:50:04', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd08e19de-d956-466c-96c9-bd827aeebd17'	System	29 Sep 2020 14:50:20
User entered 'Yes (Y)'	System	29 Sep 2020 14:50:20

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
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 'Included medication in appropriate pages.' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 04:24:03
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).	Isaac Perez (b) (4)	30 Sep 2020 14:02:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:50:12', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd08e19de-d956-466c-96c9-bd827aeebd17'	(b) (4)	
User entered '1'	System	29 Sep 2020 14:50:20
	System	29 Sep 2020 14:50:20
	System	29 Sep 2020 14:50:20

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:50:12', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd08e19de-d956-466c-96c9-bd827aeebd17'	System	29 Sep 2020 14:50:20
User entered '0'	System	29 Sep 2020 14:50:20

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:50:15', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd08e19de-d956-466c-96c9-bd827aeebd17'	System	29 Sep 2020 14:50:20
User entered '29 Sep 2020 10:50'	System	29 Sep 2020 14:50:20

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 6'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:37:51', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9f8ed97c-9ac0-4245-b16a-4c040574f284'	System	30 Sep 2020 13:39:34
User entered 'Yes (Y)'	System	30 Sep 2020 13:39:34

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:38:17', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9f8ed97c-9ac0-4245-b16a-4c040574f284'	System	30 Sep 2020 13:39:34
User entered '96.0'	System	30 Sep 2020 13:39:34

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:38:30', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9f8ed97c-9ac0-4245-b16a-4c040574f284'	System	30 Sep 2020 13:39:34
User entered 'No (N)'	System	30 Sep 2020 13:39:34

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:39:32', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9f8ed97c-9ac0-4245-b16a-4c040574f284'	System	30 Sep 2020 13:39:34
User entered '30 Sep 2020 09:39'	System	30 Sep 2020 13:39:34

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 7'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:54:12', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'a977bd62-e110-4904-bfb8-5976a4344c73'	System	30 Sep 2020 16:54:28
User entered 'Yes (Y)'	System	30 Sep 2020 16:54:28

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:54:17', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'a977bd62-e110-4904-bfb8-5976a4344c73'	System	30 Sep 2020 16:54:28
User entered '96.0'	System	30 Sep 2020 16:54:28

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:54:21', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'a977bd62-e110-4904-bfb8-5976a4344c73'	System	30 Sep 2020 16:54:28
User entered 'No (N)'	System	30 Sep 2020 16:54:28

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:54:24', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'a977bd62-e110-4904-bfb8-5976a4344c73'	System	30 Sep 2020 16:54:28
User entered '30 Sep 2020 12:54'	System	30 Sep 2020 16:54:28

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:46:50', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '46d99d0b-cd5b-4b4e-8faa-6dd5cdf92169'	System	24 Sep 2020 15:47:21
User entered 'None (1)'	System	24 Sep 2020 15:47:21

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:46:59', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '46d99d0b-cd5b-4b4e-8faa-6dd5cdf92169'	System	24 Sep 2020 15:47:21
User entered 'No (N)'	System	24 Sep 2020 15:47:21

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:47:05', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '46d99d0b-cd5b-4b4e-8faa-6dd5cdf92169'	System	24 Sep 2020 15:47:21
User entered 'No (N)'	System	24 Sep 2020 15:47:21

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:47:12', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '46d99d0b-cd5b-4b4e-8faa-6dd5cdf92169'	System	24 Sep 2020 15:47:21
User entered 'None (1)'	System	24 Sep 2020 15:47:21

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:47:18', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '46d99d0b-cd5b-4b4e-8faa-6dd5cdf92169'	System	24 Sep 2020 15:47:21
User entered '24 Sep 2020 11:47'	System	24 Sep 2020 15:47:21

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Sep 2020 11:38'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Sep 2020 14:08'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:21', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'acb7d578-fb69-4989-a4b0-42c3ef169971'	System	25 Sep 2020 03:14:38
User entered 'None (1)'	System	25 Sep 2020 03:14:38

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:27', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'acb7d578-fb69-4989-a4b0-42c3ef169971'	System	25 Sep 2020 03:14:38
User entered 'No (N)'	System	25 Sep 2020 03:14:38

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:30', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'acb7d578-fb69-4989-a4b0-42c3ef169971'	System	25 Sep 2020 03:14:38
User entered 'No (N)'	System	25 Sep 2020 03:14:38

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:33', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'acb7d578-fb69-4989-a4b0-42c3ef169971'	System	25 Sep 2020 03:14:38
User entered 'None (1)'	System	25 Sep 2020 03:14:38

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:36', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'acb7d578-fb69-4989-a4b0-42c3ef169971'	System	25 Sep 2020 03:14:38
User entered '24 Sep 2020 23:14'	System	25 Sep 2020 03:14:38

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Sep 2020 15:03'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 2'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:40:53', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '899a8f97-b40f-4230-9569-b9ad255bd85b'	System	26 Sep 2020 03:45:07
User entered 'None (1)'	System	26 Sep 2020 03:45:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:41:01', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '899a8f97-b40f-4230-9569-b9ad255bd85b'	System	26 Sep 2020 03:45:07
User entered 'No (N)'	System	26 Sep 2020 03:45:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:41:06', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '899a8f97-b40f-4230-9569-b9ad255bd85b'	System	26 Sep 2020 03:45:07
User entered 'No (N)'	System	26 Sep 2020 03:45:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:41:17', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '899a8f97-b40f-4230-9569-b9ad255bd85b'	System	26 Sep 2020 03:45:07
User entered 'None (1)'	System	26 Sep 2020 03:45:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:41:20', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '899a8f97-b40f-4230-9569-b9ad255bd85b'	System	26 Sep 2020 03:45:07
User entered '25 Sep 2020 23:41'	System	26 Sep 2020 03:45:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 3'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 4'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:32:54', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'f74a7874-25b7-4278-a614-009212c2d882'	System	28 Sep 2020 02:33:10
User entered 'None (1)'	System	28 Sep 2020 02:33:10

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:32:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'f74a7874-25b7-4278-a614-009212c2d882'	System	28 Sep 2020 02:33:10
User entered 'No (N)'	System	28 Sep 2020 02:33:10

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:33:01', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'f74a7874-25b7-4278-a614-009212c2d882'	System	28 Sep 2020 02:33:10
User entered 'No (N)'	System	28 Sep 2020 02:33:10

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:33:05', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'f74a7874-25b7-4278-a614-009212c2d882'	System	28 Sep 2020 02:33:10
User entered 'None (1)'	System	28 Sep 2020 02:33:10

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:33:07', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'f74a7874-25b7-4278-a614-009212c2d882'	System	28 Sep 2020 02:33:10
User entered '27 Sep 2020 22:33'	System	28 Sep 2020 02:33:10

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 5'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:50:21', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'f0d5dfdb-b6fa-4379-92ac-733384c2a34d'	System	29 Sep 2020 14:50:50
User entered 'None (1)'	System	29 Sep 2020 14:50:50

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:50:24', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'f0d5dfdb-b6fa-4379-92ac-733384c2a34d'	System	29 Sep 2020 14:50:50
User entered 'No (N)'	System	29 Sep 2020 14:50:50

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:50:27', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'f0d5dfdb-b6fa-4379-92ac-733384c2a34d'	System	29 Sep 2020 14:50:50
User entered 'No (N)'	System	29 Sep 2020 14:50:50

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:50:30', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'f0d5dfdb-b6fa-4379-92ac-733384c2a34d'	System	29 Sep 2020 14:50:50
User entered 'None (1)'	System	29 Sep 2020 14:50:50

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:50:32', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'f0d5dfdb-b6fa-4379-92ac-733384c2a34d'	System	29 Sep 2020 14:50:50
User entered '29 Sep 2020 10:50'	System	29 Sep 2020 14:50:50

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 6'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:39:36', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ad7957f4-fdcd-4a51-8eb6-3bab165a56b8'	System	30 Sep 2020 13:39:55
User entered 'None (1)'	System	30 Sep 2020 13:39:55

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:39:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ad7957f4-fdcd-4a51-8eb6-3bab165a56b8'	System	30 Sep 2020 13:39:55
User entered 'No (N)'	System	30 Sep 2020 13:39:55

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:39:46', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ad7957f4-fdcd-4a51-8eb6-3bab165a56b8'	System	30 Sep 2020 13:39:55
User entered 'No (N)'	System	30 Sep 2020 13:39:55

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:39:49', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ad7957f4-fdcd-4a51-8eb6-3bab165a56b8'	System	30 Sep 2020 13:39:55
User entered 'None (1)'	System	30 Sep 2020 13:39:55

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:39:53', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ad7957f4-fdcd-4a51-8eb6-3bab165a56b8'	System	30 Sep 2020 13:39:55
User entered '30 Sep 2020 09:39'	System	30 Sep 2020 13:39:55

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 7'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:54:28', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '95df0ba9-2cef-4130-ba79-d61b9c18cc10'	System	30 Sep 2020 16:54:43
User entered 'None (1)'	System	30 Sep 2020 16:54:43

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:54:30', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '95df0ba9-2cef-4130-ba79-d61b9c18cc10'	System	30 Sep 2020 16:54:43
User entered 'No (N)'	System	30 Sep 2020 16:54:43

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:54:34', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '95df0ba9-2cef-4130-ba79-d61b9c18cc10'	System	30 Sep 2020 16:54:43
User entered 'No (N)'	System	30 Sep 2020 16:54:43

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:54:37', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '95df0ba9-2cef-4130-ba79-d61b9c18cc10'	System	30 Sep 2020 16:54:43
User entered 'None (1)'	System	30 Sep 2020 16:54:43

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:54:40', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '95df0ba9-2cef-4130-ba79-d61b9c18cc10'	System	30 Sep 2020 16:54:43
User entered '30 Sep 2020 12:54'	System	30 Sep 2020 16:54:43

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:47:27', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '320d9b69-9be0-4e2f-afdc-14653430d530'	System	24 Sep 2020 15:47:48
User entered 'None (0)'	System	24 Sep 2020 15:47:48

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:47:32', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '320d9b69-9be0-4e2f-afdc-14653430d530'	System	24 Sep 2020 15:47:48
User entered 'None (0)'	System	24 Sep 2020 15:47:48

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:47:34', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '320d9b69-9be0-4e2f-afdc-14653430d530'	System	24 Sep 2020 15:47:48
User entered 'None (0)'	System	24 Sep 2020 15:47:48

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:47:37', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '320d9b69-9be0-4e2f-afdc-14653430d530'	System	24 Sep 2020 15:47:48
User entered 'None (0)'	System	24 Sep 2020 15:47:48

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:47:39', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '320d9b69-9be0-4e2f-afdc-14653430d530'	System	24 Sep 2020 15:47:48
User entered 'None (0)'	System	24 Sep 2020 15:47:48

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:47:41', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '320d9b69-9be0-4e2f-afdc-14653430d530'	System	24 Sep 2020 15:47:48
User entered 'None (0)'	System	24 Sep 2020 15:47:48

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:47:44', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '320d9b69-9be0-4e2f-afdc-14653430d530'	System	24 Sep 2020 15:47:48
User entered 'No (N)'	System	24 Sep 2020 15:47:48

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T11:47:47', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '320d9b69-9be0-4e2f-afdc-14653430d530'	System	24 Sep 2020 15:47:48
User entered '24 Sep 2020 11:47'	System	24 Sep 2020 15:47:48

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Sep 2020 11:38'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Sep 2020 14:08'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:39', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd15f3c27-6225-47e8-9ead-6a89412f165b'	System	25 Sep 2020 03:15:07
User entered 'None (0)'	System	25 Sep 2020 03:15:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd15f3c27-6225-47e8-9ead-6a89412f165b'	System	25 Sep 2020 03:15:07
User entered 'None (0)'	System	25 Sep 2020 03:15:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:45', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd15f3c27-6225-47e8-9ead-6a89412f165b'	System	25 Sep 2020 03:15:07
User entered 'None (0)'	System	25 Sep 2020 03:15:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:47', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd15f3c27-6225-47e8-9ead-6a89412f165b'	System	25 Sep 2020 03:15:07
User entered 'None (0)'	System	25 Sep 2020 03:15:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:49', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd15f3c27-6225-47e8-9ead-6a89412f165b'	System	25 Sep 2020 03:15:07
User entered 'None (0)'	System	25 Sep 2020 03:15:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:51', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd15f3c27-6225-47e8-9ead-6a89412f165b'	System	25 Sep 2020 03:15:07
User entered 'None (0)'	System	25 Sep 2020 03:15:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:14:59', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd15f3c27-6225-47e8-9ead-6a89412f165b'	System	25 Sep 2020 03:15:07
User entered 'No (N)'	System	25 Sep 2020 03:15:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-24T23:15:02', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd15f3c27-6225-47e8-9ead-6a89412f165b'	System	25 Sep 2020 03:15:07
User entered '24 Sep 2020 23:15'	System	25 Sep 2020 03:15:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Sep 2020 15:03'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 2'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:41:25', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '69634aa8-dba2-40b1-a4d1-dd63b387bdab'	System	26 Sep 2020 03:45:04
User entered 'None (0)'	System	26 Sep 2020 03:45:04

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:41:28', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '69634aa8-dba2-40b1-a4d1-dd63b387bdab'	System	26 Sep 2020 03:45:04
User entered 'None (0)'	System	26 Sep 2020 03:45:04

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:41:30', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '69634aa8-dba2-40b1-a4d1-dd63b387bdab'	System	26 Sep 2020 03:45:04
User entered 'None (0)'	System	26 Sep 2020 03:45:04

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:41:34', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '69634aa8-dba2-40b1-a4d1-dd63b387bdab'	System	26 Sep 2020 03:45:04
User entered 'None (0)'	System	26 Sep 2020 03:45:04

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:41:38', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '69634aa8-dba2-40b1-a4d1-dd63b387bdab'	System	26 Sep 2020 03:45:04
User entered 'None (0)'	System	26 Sep 2020 03:45:04

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:41:44', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '69634aa8-dba2-40b1-a4d1-dd63b387bdab'	System	26 Sep 2020 03:45:04
User entered 'None (0)'	System	26 Sep 2020 03:45:04

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:42:08', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '69634aa8-dba2-40b1-a4d1-dd63b387bdab'	System	26 Sep 2020 03:45:04
User entered 'No (N)'	System	26 Sep 2020 03:45:04

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-25T23:42:11', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '69634aa8-dba2-40b1-a4d1-dd63b387bdab'	System	26 Sep 2020 03:45:04
User entered '25 Sep 2020 23:42'	System	26 Sep 2020 03:45:04

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 3'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 4'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:33:11', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0d065a77-fb52-492e-855f-817bb0b9c21a'	System	28 Sep 2020 02:33:46
User entered 'None (0)'	System	28 Sep 2020 02:33:46

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:33:13', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0d065a77-fb52-492e-855f-817bb0b9c21a'	System	28 Sep 2020 02:33:46
User entered 'None (0)'	System	28 Sep 2020 02:33:46

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:33:21', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0d065a77-fb52-492e-855f-817bb0b9c21a'	System	28 Sep 2020 02:33:46
User entered 'No interference with activity (1)'	System	28 Sep 2020 02:33:46

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:33:29', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0d065a77-fb52-492e-855f-817bb0b9c21a'	System	28 Sep 2020 02:33:46
User entered 'No interference with activity (1)'	System	28 Sep 2020 02:33:46

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:33:33', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0d065a77-fb52-492e-855f-817bb0b9c21a'	System	28 Sep 2020 02:33:46
User entered 'None (0)'	System	28 Sep 2020 02:33:46

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:33:37', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0d065a77-fb52-492e-855f-817bb0b9c21a'	System	28 Sep 2020 02:33:46
User entered 'None (0)'	System	28 Sep 2020 02:33:46

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:33:40', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0d065a77-fb52-492e-855f-817bb0b9c21a'	System	28 Sep 2020 02:33:46
User entered 'No (N)'	System	28 Sep 2020 02:33:46

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-27T22:33:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0d065a77-fb52-492e-855f-817bb0b9c21a'	System	28 Sep 2020 02:33:46
User entered '27 Sep 2020 22:33'	System	28 Sep 2020 02:33:46

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 5'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:50:41', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'eb0caa24-b6ef-48c1-b087-c91fa4cd1bbf'	System	29 Sep 2020 14:51:20
User entered 'No interference with activity (1)'	System	29 Sep 2020 14:51:20

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:50:50', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'eb0caa24-b6ef-48c1-b087-c91fa4cd1bbf'	System	29 Sep 2020 14:51:20
User entered 'Some interference with activity (2)'	System	29 Sep 2020 14:51:20

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:50:58', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'eb0caa24-b6ef-48c1-b087-c91fa4cd1bbf'	System	29 Sep 2020 14:51:20
User entered 'Some interference with activity (2)'	System	29 Sep 2020 14:51:20

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:51:03', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'eb0caa24-b6ef-48c1-b087-c91fa4cd1bbf'	System	29 Sep 2020 14:51:20
User entered 'Some interference with activity (2)'	System	29 Sep 2020 14:51:20

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:51:07', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'eb0caa24-b6ef-48c1-b087-c91fa4cd1bbf'	System	29 Sep 2020 14:51:20
User entered 'None (0)'	System	29 Sep 2020 14:51:20

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:51:10', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'eb0caa24-b6ef-48c1-b087-c91fa4cd1bbf'	System	29 Sep 2020 14:51:20
User entered 'None (0)'	System	29 Sep 2020 14:51:20

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:51:14', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'eb0caa24-b6ef-48c1-b087-c91fa4cd1bbf'	System	29 Sep 2020 14:51:20
User entered 'No (N)'	System	29 Sep 2020 14:51:20

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-29T10:51:16', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'eb0caa24-b6ef-48c1-b087-c91fa4cd1bbf'	System	29 Sep 2020 14:51:20
User entered '29 Sep 2020 10:51'	System	29 Sep 2020 14:51:20

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 6'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:39:58', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6df82d12-f8ed-4f16-9bc0-a1e636dbd13e'	System	30 Sep 2020 13:40:41
User entered 'None (0)'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:40:10', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6df82d12-f8ed-4f16-9bc0-a1e636dbd13e'	System	30 Sep 2020 13:40:41
User entered 'None (0)'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:40:13', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6df82d12-f8ed-4f16-9bc0-a1e636dbd13e'	System	30 Sep 2020 13:40:41
User entered 'None (0)'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:40:18', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6df82d12-f8ed-4f16-9bc0-a1e636dbd13e'	System	30 Sep 2020 13:40:41
User entered 'No interference with activity (1)'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:40:20', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6df82d12-f8ed-4f16-9bc0-a1e636dbd13e'	System	30 Sep 2020 13:40:41
User entered 'None (0)'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:40:23', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6df82d12-f8ed-4f16-9bc0-a1e636dbd13e'	System	30 Sep 2020 13:40:41
User entered 'None (0)'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:40:34', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6df82d12-f8ed-4f16-9bc0-a1e636dbd13e'	System	30 Sep 2020 13:40:41
User entered 'No (N)'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T09:40:38', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6df82d12-f8ed-4f16-9bc0-a1e636dbd13e'	System	30 Sep 2020 13:40:41
User entered '30 Sep 2020 09:40'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	24 Sep 2020 15:32:07
User entered 'Day 7'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:54:43', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44e1793d-f6d1-4a0f-b40d-05872f9f17ff'	System	30 Sep 2020 16:55:16
User entered 'None (0)'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:54:48', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44e1793d-f6d1-4a0f-b40d-05872f9f17ff'	System	30 Sep 2020 16:55:16
User entered 'No interference with activity (1)'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:54:55', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44e1793d-f6d1-4a0f-b40d-05872f9f17ff'	System	30 Sep 2020 16:55:16
User entered 'None (0)'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:55:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44e1793d-f6d1-4a0f-b40d-05872f9f17ff'	System	30 Sep 2020 16:55:16
User entered 'No interference with activity (1)'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:55:02', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44e1793d-f6d1-4a0f-b40d-05872f9f17ff'	System	30 Sep 2020 16:55:16
User entered 'None (0)'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:55:04', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44e1793d-f6d1-4a0f-b40d-05872f9f17ff'	System	30 Sep 2020 16:55:16
User entered 'None (0)'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:55:09', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44e1793d-f6d1-4a0f-b40d-05872f9f17ff'	System	30 Sep 2020 16:55:16
User entered 'No (N)'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-09-30T12:55:11', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44e1793d-f6d1-4a0f-b40d-05872f9f17ff'	System	30 Sep 2020 16:55:16
User entered '30 Sep 2020 12:55'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 15:32:07

US3632107

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	30 Sep 2020 16:55:16
User entered 'Day 8'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-01T12:19:20', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'edd53ae8-2b0f-4a77-ab86-d2730e49ccb9'	System	01 Oct 2020 16:19:37
User entered 'None (0)'	System	01 Oct 2020 16:19:37

US3632107

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-01T12:19:33', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'edd53ae8-2b0f-4a77-ab86-d2730e49ccb9'	System	01 Oct 2020 16:19:37
User entered '01 Oct 2020 12:19'	System	01 Oct 2020 16:19:37

US3632107

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	30 Sep 2020 13:40:41
User entered 'Day 8'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:54:03

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-01T12:19:38', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'a1d60f57-c92d-4d3d-a63c-fdcddedebfb17'	System	01 Oct 2020 16:19:43
User entered 'No interference with activity (1)'	System	01 Oct 2020 16:19:43

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-01T12:19:40', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'a1d60f57-c92d-4d3d-a63c-fdcddedebfb17'	System	01 Oct 2020 16:19:43
User entered '01 Oct 2020 12:19'	System	01 Oct 2020 16:19:43

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	30 Sep 2020 16:55:16
User entered 'Day 9'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:54:03

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	01 Oct 2020 16:19:43
User entered 'Day 10'	System	01 Oct 2020 16:19:43

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:54:03

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:19:43

US3632107

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:19:43

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	30 Sep 2020 13:40:41
User entered 'Day 8'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-01T12:19:44', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '94461935-e7d5-41d2-a31e-80ff1c770963'	System	01 Oct 2020 16:19:48
User entered 'No (N)'	System	01 Oct 2020 16:19:48

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-01T12:19:46', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '94461935-e7d5-41d2-a31e-80ff1c770963'	System	01 Oct 2020 16:19:48
User entered '01 Oct 2020 12:19'	System	01 Oct 2020 16:19:48

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 13:40:41

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
DataPoint Activated.	System	01 Oct 2020 16:19:43
DataPoint Inactivated.	System	01 Oct 2020 16:19:37
Data entry locked.	System	30 Sep 2020 16:55:16
User entered 'Day 9'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
DataPoint Activated.	System	01 Oct 2020 16:19:43
DataPoint Inactivated.	System	01 Oct 2020 16:19:37

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
DataPoint Activated.	System	01 Oct 2020 16:19:43
DataPoint Inactivated.	System	01 Oct 2020 16:19:37

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
DataPoint Activated.	System	01 Oct 2020 16:19:43
DataPoint Inactivated.	System	01 Oct 2020 16:19:37
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
DataPoint Activated.	System	01 Oct 2020 16:19:43
DataPoint Inactivated.	System	01 Oct 2020 16:19:37
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:55:16

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	01 Oct 2020 16:19:43
User entered 'Day 10'	System	01 Oct 2020 16:19:43

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:19:43

US3632107

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:19:43

US3632107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	08 Oct 2020 20:13:56

US3632107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 16:46:29
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Made call a day early and followed up via text on October 1.' (Site from System).	Christina Bacher (b) (4)	08 Oct 2020 20:16:03
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Oct 2020 20:13:56
User entered '30 Sep 2020'	Christina Bacher (b) (4)	08 Oct 2020 20:13:56

US3632107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Contact Made (CONTACT MADE)'	Christina Bacher (b) (4)	08 Oct 2020 20:13:56

US3632107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	08 Oct 2020 20:13:56

US3632107

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	08 Oct 2020 20:16:16

US3632107

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'I'	System	08 Oct 2020 20:16:16

US3632107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	08 Oct 2020 20:16:30

US3632107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '8 Oct 2020'	Christina Bacher (b) (4)	08 Oct 2020 20:16:30

US3632107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Contact Made (CONTACT MADE)'	Christina Bacher (b) (4)	08 Oct 2020 20:16:30

US3632107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	08 Oct 2020 20:16:30

US3632107

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	08 Oct 2020 20:16:35

US3632107

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'I'	System	08 Oct 2020 20:16:35

US3632107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	15 Oct 2020 16:54:28

US3632107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '15 Oct 2020'	Christina Bacher (b) (4)	15 Oct 2020 16:54:28

US3632107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Contact Made (CONTACT MADE)'	Christina Bacher (b) (4)	15 Oct 2020 16:54:28

US3632107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	15 Oct 2020 16:54:28

US3632107

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	15 Oct 2020 16:54:32

US3632107

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'I'	System	15 Oct 2020 16:54:32

US3632107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Isaac Perez (b) (4)	20 Oct 2020 13:56:49

US3632107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '20 Oct 2020'	Isaac Perez (b) (4)	20 Oct 2020 13:56:49

US3632107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Clinic (Clinic)'	Isaac Perez (b) (4)	20 Oct 2020 13:56:49

US3632107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'VISIT2'	System	20 Oct 2020 13:56:49

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User accepted default value 'Pre-Dose (PREDOSE)'	Isaac Perez (b) (4) (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '20 Oct 2020'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '8:44'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered '20 Oct 2020 8:44'	System	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '97.3' F	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Oral (Oral)'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '59'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'bpm'	System	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '14'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'breaths/min'	System	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '136'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'mmHg'	System	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '69'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'mmHg'	System	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User accepted default value 'Post-Dose (POSTDOSE)'	Isaac Perez (b) (4) (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '20 Oct 2020'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '11:29'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered '20 Oct 2020 11:29'	System	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '97.2' F	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Oral (Oral)'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '56'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'bpm'	System	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '10'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'breaths/min'	System	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '133'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'mmHg'	System	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '72'	Isaac Perez (b) (4)	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'mmHg'	System	20 Oct 2020 15:38:47

US3632107

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Isaac Perez (b) (4)	20 Oct 2020 13:57:02

US3632107

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '20 Oct 2020'	Isaac Perez (b) (4)	20 Oct 2020 13:57:02

US3632107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Isaac Perez (b) (4)	20 Oct 2020 15:01:25

US3632107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Isaac Perez (b) (4)	20 Oct 2020 15:01:25

US3632107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

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)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Isaac Perez (b) (4)	20 Oct 2020 15:01:25

US3632107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'MRNA-1273 OR PLACEBO'	System	20 Oct 2020 15:01:25

US3632107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '20 Oct 2020'	Isaac Perez (b) (4)	20 Oct 2020 15:01:25

US3632107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '10:57'	Isaac Perez (b) (4)	20 Oct 2020 15:01:25

US3632107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered '20 Oct 2020 10:57'	System	20 Oct 2020 15:01:25

US3632107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Left Arm (LEFT ARM)'	Isaac Perez (b) (4)	20 Oct 2020 15:01:25

US3632107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'ONCE'	System	20 Oct 2020 15:01:25

US3632107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'INTRAMUSCULAR'	System	20 Oct 2020 15:01:25

US3632107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Isaac Perez (b) (4)	20 Oct 2020 14:01:21

US3632107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '20 Oct 2020'	Isaac Perez (b) (4)	20 Oct 2020 14:01:21

US3632107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '9:07'	Isaac Perez (b) (4)	20 Oct 2020 14:01:21

US3632107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered '20 Oct 2020 9:07'	System	20 Oct 2020 14:01:21

US3632107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:54:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '20 Oct 2020'	Isaac Perez (b) (4)	20 Oct 2020 14:01:39

US3632107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:54:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Isaac Perez (b) (4) (b) (4)	20 Oct 2020 14:01:39

US3632107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:54:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Isaac Perez (b) (4)	20 Oct 2020 14:01:39

US3632107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:54:03

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '9:10'	Isaac Perez (b) (4)	20 Oct 2020 14:01:39

US3632107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:54:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered '20 Oct 2020 9:10'	System	20 Oct 2020 14:01:39

US3632107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:54:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Isaac Perez (b) (4) (b) (4)	20 Oct 2020 14:01:39

US3632107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:54:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	Isaac Perez (b) (4)	20 Oct 2020 14:01:39

US3632107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:54:03

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Isaac Perez (b) (4)	20 Oct 2020 14:01:39

US3632107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:54:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered empty.	System	20 Oct 2020 14:01:39

US3632107

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Isaac Perez (b) (4)	20 Oct 2020 15:38:55

US3632107

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'I'	System	20 Oct 2020 15:38:55

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:23:59', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '70756907-738e-4561-b6ae-c8f858983fff'	System	20 Oct 2020 15:24:13
User entered 'Yes (Y)'	System	20 Oct 2020 15:24:13

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:24:04', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '70756907-738e-4561-b6ae-c8f858983fff'	System	20 Oct 2020 15:24:13
User entered '97.2'	System	20 Oct 2020 15:24:13

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:24:07', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '70756907-738e-4561-b6ae-c8f858983fff'	System	20 Oct 2020 15:24:13
User entered 'No (N)'	System	20 Oct 2020 15:24:13

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:24:11', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '70756907-738e-4561-b6ae-c8f858983fff'	System	20 Oct 2020 15:24:13
User entered '20 Oct 2020 11:24'	System	20 Oct 2020 15:24:13

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '20 Oct 2020 11:17'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '20 Oct 2020 13:47'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:14:21', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '614f8224-155b-4b80-8838-cc7c4e31ca29'	System	21 Oct 2020 03:14:38
User entered 'Yes (Y)'	System	21 Oct 2020 03:14:38

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:14:29', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '614f8224-155b-4b80-8838-cc7c4e31ca29'	System	21 Oct 2020 03:14:38
User entered '96.7'	System	21 Oct 2020 03:14:38

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:14:32', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '614f8224-155b-4b80-8838-cc7c4e31ca29'	System	21 Oct 2020 03:14:38
User entered 'No (N)'	System	21 Oct 2020 03:14:38

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:14:35', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '614f8224-155b-4b80-8838-cc7c4e31ca29'	System	21 Oct 2020 03:14:38
User entered '20 Oct 2020 23:14'	System	21 Oct 2020 03:14:38

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '20 Oct 2020 14:42'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 2'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:41:17', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4b5b93ea-1481-4f28-be15-2a55c3a77e9b'	System	22 Oct 2020 13:41:37
User entered 'Yes (Y)'	System	22 Oct 2020 13:41:37

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:41:26', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4b5b93ea-1481-4f28-be15-2a55c3a77e9b'	System	22 Oct 2020 13:41:37
User entered '96.5'	System	22 Oct 2020 13:41:37

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:41:30', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4b5b93ea-1481-4f28-be15-2a55c3a77e9b'	System	22 Oct 2020 13:41:37
User entered 'No (N)'	System	22 Oct 2020 13:41:37

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:41:34', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4b5b93ea-1481-4f28-be15-2a55c3a77e9b'	System	22 Oct 2020 13:41:37
User entered '22 Oct 2020 09:41'	System	22 Oct 2020 13:41:37

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 3'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:47:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c3a4878e-0709-4f13-b0bc-d48a7d622c08'	System	23 Oct 2020 02:47:59
User entered 'Yes (Y)'	System	23 Oct 2020 02:47:59

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:47:49', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c3a4878e-0709-4f13-b0bc-d48a7d622c08'	System	23 Oct 2020 02:47:59
User entered '98.2'	System	23 Oct 2020 02:47:59

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:47:52', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c3a4878e-0709-4f13-b0bc-d48a7d622c08'	System	23 Oct 2020 02:47:59
User entered 'No (N)'	System	23 Oct 2020 02:47:59

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:47:54', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c3a4878e-0709-4f13-b0bc-d48a7d622c08'	System	23 Oct 2020 02:47:59
User entered '22 Oct 2020 22:47'	System	23 Oct 2020 02:47:59

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 4'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:45:40', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'a3a70fc7-bf50-4809-86cf-67ff5f679289'	System	24 Oct 2020 06:46:02
User entered 'Yes (Y)'	System	24 Oct 2020 06:46:02

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:45:48', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'a3a70fc7-bf50-4809-86cf-67ff5f679289'	System	24 Oct 2020 06:46:02
User entered '97.5'	System	24 Oct 2020 06:46:02

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:45:53', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'a3a70fc7-bf50-4809-86cf-67ff5f679289'	System	24 Oct 2020 06:46:02
User entered 'No (N)'	System	24 Oct 2020 06:46:02

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'a3a70fc7-bf50-4809-86cf-67ff5f679289'	System	24 Oct 2020 06:46:02
User entered '24 Oct 2020 02:46'	System	24 Oct 2020 06:46:02

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 5'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:50:56', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0fecffce-d6ba-4611-af34-b406f1696f93'	System	25 Oct 2020 00:51:15
User entered 'Yes (Y)'	System	25 Oct 2020 00:51:15

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:05', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0fecffce-d6ba-4611-af34-b406f1696f93'	System	25 Oct 2020 00:51:15
User entered '97.5'	System	25 Oct 2020 00:51:15

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:10', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0fecffce-d6ba-4611-af34-b406f1696f93'	System	25 Oct 2020 00:51:15
User entered 'No (N)'	System	25 Oct 2020 00:51:15

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:13', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0fecffce-d6ba-4611-af34-b406f1696f93'	System	25 Oct 2020 00:51:15
User entered '24 Oct 2020 20:51'	System	25 Oct 2020 00:51:15

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 6'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:05:55', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '5f1c4f3a-d635-4d07-aeca-3d5d0ce17de3'	System	26 Oct 2020 01:06:10
User entered 'Yes (Y)'	System	26 Oct 2020 01:06:10

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:01', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '5f1c4f3a-d635-4d07-aeca-3d5d0ce17de3'	System	26 Oct 2020 01:06:10
User entered '96.8'	System	26 Oct 2020 01:06:10

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:03', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '5f1c4f3a-d635-4d07-aeca-3d5d0ce17de3'	System	26 Oct 2020 01:06:10
User entered 'No (N)'	System	26 Oct 2020 01:06:10

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:08', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '5f1c4f3a-d635-4d07-aeca-3d5d0ce17de3'	System	26 Oct 2020 01:06:10
User entered '25 Oct 2020 21:06'	System	26 Oct 2020 01:06:10

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 7'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:19', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9b9ea1c1-67f2-4bd2-83b8-2f13f350a51f'	System	27 Oct 2020 01:14:36
User entered 'Yes (Y)'	System	27 Oct 2020 01:14:36

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:25', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9b9ea1c1-67f2-4bd2-83b8-2f13f350a51f' User entered '98.5'	System	27 Oct 2020 01:14:36
	System	27 Oct 2020 01:14:36

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:27', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9b9ea1c1-67f2-4bd2-83b8-2f13f350a51f'	System	27 Oct 2020 01:14:36
User entered 'No (N)'	System	27 Oct 2020 01:14:36

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:30', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9b9ea1c1-67f2-4bd2-83b8-2f13f350a51f'	System	27 Oct 2020 01:14:36
User entered '26 Oct 2020 21:14'	System	27 Oct 2020 01:14:36

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:24:17', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'e2cfee9f-9afb-435d-88f1-e70ab4a331ac'	System	20 Oct 2020 15:24:44
User entered 'None (1)'	System	20 Oct 2020 15:24:44

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:24:26', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'e2cfee9f-9afb-435d-88f1-e70ab4a331ac'	System	20 Oct 2020 15:24:44
User entered 'No (N)'	System	20 Oct 2020 15:24:44

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:24:29', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'e2cfee9f-9afb-435d-88f1-e70ab4a331ac'	System	20 Oct 2020 15:24:44
User entered 'No (N)'	System	20 Oct 2020 15:24:44

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:24:38', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'e2cfee9f-9afb-435d-88f1-e70ab4a331ac'	System	20 Oct 2020 15:24:44
User entered 'None (1)'	System	20 Oct 2020 15:24:44

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:24:41', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'e2cfee9f-9afb-435d-88f1-e70ab4a331ac'	System	20 Oct 2020 15:24:44
User entered '20 Oct 2020 11:24'	System	20 Oct 2020 15:24:44

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '20 Oct 2020 11:17'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '20 Oct 2020 13:47'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:14:38', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4824cbd7-0701-4f33-8976-0dd7b8b8d9f0'	System	21 Oct 2020 03:14:52
User entered 'None (1)'	System	21 Oct 2020 03:14:52

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:14:41', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4824cbd7-0701-4f33-8976-0dd7b8b8d9f0'	System	21 Oct 2020 03:14:52
User entered 'No (N)'	System	21 Oct 2020 03:14:52

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:14:43', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4824cbd7-0701-4f33-8976-0dd7b8b8d9f0'	System	21 Oct 2020 03:14:52
User entered 'No (N)'	System	21 Oct 2020 03:14:52

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:14:45', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4824cbd7-0701-4f33-8976-0dd7b8b8d9f0'	System	21 Oct 2020 03:14:52
User entered 'None (1)'	System	21 Oct 2020 03:14:52

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:14:49', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4824cbd7-0701-4f33-8976-0dd7b8b8d9f0'	System	21 Oct 2020 03:14:52
User entered '20 Oct 2020 23:14'	System	21 Oct 2020 03:14:52

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '20 Oct 2020 14:42'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 2'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:41:37', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1df4468d-91fa-4200-8c4d-7e1caf81fbd9'	System	22 Oct 2020 13:42:12
User entered 'None (1)'	System	22 Oct 2020 13:42:12

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:41:51', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1df4468d-91fa-4200-8c4d-7e1caf81fbd9'	System	22 Oct 2020 13:42:12
User entered 'No (N)'	System	22 Oct 2020 13:42:12

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:42:03', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1df4468d-91fa-4200-8c4d-7e1caf81fbd9'	System	22 Oct 2020 13:42:12
User entered 'No (N)'	System	22 Oct 2020 13:42:12

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:42:07', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1df4468d-91fa-4200-8c4d-7e1caf81fbd9'	System	22 Oct 2020 13:42:12
User entered 'None (1)'	System	22 Oct 2020 13:42:12

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:42:11', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1df4468d-91fa-4200-8c4d-7e1caf81fbd9'	System	22 Oct 2020 13:42:12
User entered '22 Oct 2020 09:42'	System	22 Oct 2020 13:42:12

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 3'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:03', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'af1f5d00-f4ad-464d-ab15-67274c0441cd'	System	23 Oct 2020 02:48:15
User entered 'None (1)'	System	23 Oct 2020 02:48:15

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:05', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'af1f5d00-f4ad-464d-ab15-67274c0441cd'	System	23 Oct 2020 02:48:15
User entered 'No (N)'	System	23 Oct 2020 02:48:15

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:07', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'af1f5d00-f4ad-464d-ab15-67274c0441cd'	System	23 Oct 2020 02:48:15
User entered 'No (N)'	System	23 Oct 2020 02:48:15

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:08', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'af1f5d00-f4ad-464d-ab15-67274c0441cd'	System	23 Oct 2020 02:48:15
User entered 'None (1)'	System	23 Oct 2020 02:48:15

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:11', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'af1f5d00-f4ad-464d-ab15-67274c0441cd'	System	23 Oct 2020 02:48:15
User entered '22 Oct 2020 22:48'	System	23 Oct 2020 02:48:15

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 4'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:04', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'df7de08b-edac-470c-b8ee-aa0376d89ff8'	System	24 Oct 2020 06:46:19
User entered 'None (1)'	System	24 Oct 2020 06:46:19

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:07', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'df7de08b-edac-470c-b8ee-aa0376d89ff8'	System	24 Oct 2020 06:46:19
User entered 'No (N)'	System	24 Oct 2020 06:46:19

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:09', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'df7de08b-edac-470c-b8ee-aa0376d89ff8'	System	24 Oct 2020 06:46:19
User entered 'No (N)'	System	24 Oct 2020 06:46:19

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:12', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'df7de08b-edac-470c-b8ee-aa0376d89ff8'	System	24 Oct 2020 06:46:19
User entered 'None (1)'	System	24 Oct 2020 06:46:19

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:17', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'df7de08b-edac-470c-b8ee-aa0376d89ff8'	System	24 Oct 2020 06:46:19
User entered '24 Oct 2020 02:46'	System	24 Oct 2020 06:46:19

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 5'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:18', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '7b5ffcd6-7f41-4614-9758-e1f203bc3783'	System	25 Oct 2020 00:51:35
User entered 'None (1)'	System	25 Oct 2020 00:51:35

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:21', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '7b5ffcd6-7f41-4614-9758-e1f203bc3783'	System	25 Oct 2020 00:51:35
User entered 'No (N)'	System	25 Oct 2020 00:51:35

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:23', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '7b5ffcd6-7f41-4614-9758-e1f203bc3783'	System	25 Oct 2020 00:51:35
User entered 'No (N)'	System	25 Oct 2020 00:51:35

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:27', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '7b5ffcd6-7f41-4614-9758-e1f203bc3783'	System	25 Oct 2020 00:51:35
User entered 'None (1)'	System	25 Oct 2020 00:51:35

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:33', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '7b5ffcd6-7f41-4614-9758-e1f203bc3783'	System	25 Oct 2020 00:51:35
User entered '24 Oct 2020 20:51'	System	25 Oct 2020 00:51:35

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 6'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:12', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44d45d20-8911-4922-a32e-e1f3d95e08d8'	System	26 Oct 2020 01:06:24
User entered 'None (1)'	System	26 Oct 2020 01:06:24

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:15', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44d45d20-8911-4922-a32e-e1f3d95e08d8'	System	26 Oct 2020 01:06:24
User entered 'No (N)'	System	26 Oct 2020 01:06:24

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:17', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44d45d20-8911-4922-a32e-e1f3d95e08d8'	System	26 Oct 2020 01:06:24
User entered 'No (N)'	System	26 Oct 2020 01:06:24

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:20', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44d45d20-8911-4922-a32e-e1f3d95e08d8'	System	26 Oct 2020 01:06:24
User entered 'None (1)'	System	26 Oct 2020 01:06:24

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:22', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '44d45d20-8911-4922-a32e-e1f3d95e08d8'	System	26 Oct 2020 01:06:24
User entered '25 Oct 2020 21:06'	System	26 Oct 2020 01:06:24

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 7'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:33', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '724f8cdb-e099-4a2d-a45b-3ce930d389e2'	System	27 Oct 2020 01:14:46
User entered 'None (1)'	System	27 Oct 2020 01:14:46

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:36', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '724f8cdb-e099-4a2d-a45b-3ce930d389e2'	System	27 Oct 2020 01:14:46
User entered 'No (N)'	System	27 Oct 2020 01:14:46

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:37', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '724f8cdb-e099-4a2d-a45b-3ce930d389e2'	System	27 Oct 2020 01:14:46
User entered 'No (N)'	System	27 Oct 2020 01:14:46

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:39', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '724f8cdb-e099-4a2d-a45b-3ce930d389e2'	System	27 Oct 2020 01:14:46
User entered 'None (1)'	System	27 Oct 2020 01:14:46

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '724f8cdb-e099-4a2d-a45b-3ce930d389e2'	System	27 Oct 2020 01:14:46
User entered '26 Oct 2020 21:14'	System	27 Oct 2020 01:14:46

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:24:45', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4f5d651f-0e0e-4b3a-960a-398a350dee73'	System	20 Oct 2020 15:25:13
User entered 'None (0)'	System	20 Oct 2020 15:25:13

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:24:54', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4f5d651f-0e0e-4b3a-960a-398a350dee73'	System	20 Oct 2020 15:25:13
User entered 'None (0)'	System	20 Oct 2020 15:25:13

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:24:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4f5d651f-0e0e-4b3a-960a-398a350dee73'	System	20 Oct 2020 15:25:13
User entered 'None (0)'	System	20 Oct 2020 15:25:13

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:24:59', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4f5d651f-0e0e-4b3a-960a-398a350dee73'	System	20 Oct 2020 15:25:13
User entered 'None (0)'	System	20 Oct 2020 15:25:13

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:25:01', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4f5d651f-0e0e-4b3a-960a-398a350dee73'	System	20 Oct 2020 15:25:13
User entered 'None (0)'	System	20 Oct 2020 15:25:13

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:25:04', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4f5d651f-0e0e-4b3a-960a-398a350dee73'	System	20 Oct 2020 15:25:13
User entered 'None (0)'	System	20 Oct 2020 15:25:13

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:25:06', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4f5d651f-0e0e-4b3a-960a-398a350dee73'	System	20 Oct 2020 15:25:13
User entered 'No (N)'	System	20 Oct 2020 15:25:13

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T11:25:09', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4f5d651f-0e0e-4b3a-960a-398a350dee73'	System	20 Oct 2020 15:25:13
User entered '20 Oct 2020 11:25'	System	20 Oct 2020 15:25:13

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '20 Oct 2020 11:17'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '20 Oct 2020 13:47'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 1, after vaccination (at home)'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:14:53', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6ab0f32e-98d8-4666-9485-b62842af7a0a'	System	21 Oct 2020 03:15:14
User entered 'None (0)'	System	21 Oct 2020 03:15:14

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:14:55', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6ab0f32e-98d8-4666-9485-b62842af7a0a'	System	21 Oct 2020 03:15:14
User entered 'None (0)'	System	21 Oct 2020 03:15:14

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:14:59', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6ab0f32e-98d8-4666-9485-b62842af7a0a'	System	21 Oct 2020 03:15:14
User entered 'None (0)'	System	21 Oct 2020 03:15:14

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:15:02', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6ab0f32e-98d8-4666-9485-b62842af7a0a'	System	21 Oct 2020 03:15:14
User entered 'None (0)'	System	21 Oct 2020 03:15:14

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:15:04', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6ab0f32e-98d8-4666-9485-b62842af7a0a'	System	21 Oct 2020 03:15:14
User entered 'None (0)'	System	21 Oct 2020 03:15:14

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:15:07', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6ab0f32e-98d8-4666-9485-b62842af7a0a'	System	21 Oct 2020 03:15:14
User entered 'None (0)'	System	21 Oct 2020 03:15:14

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:15:09', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6ab0f32e-98d8-4666-9485-b62842af7a0a'	System	21 Oct 2020 03:15:14
User entered 'No (N)'	System	21 Oct 2020 03:15:14

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-20T23:15:12', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '6ab0f32e-98d8-4666-9485-b62842af7a0a'	System	21 Oct 2020 03:15:14
User entered '20 Oct 2020 23:15'	System	21 Oct 2020 03:15:14

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '20 Oct 2020 14:42'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 2'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:42:16', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ec1b6545-c2f6-4696-8c74-9a09598c762a'	System	22 Oct 2020 13:42:41
User entered 'None (0)'	System	22 Oct 2020 13:42:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:42:18', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ec1b6545-c2f6-4696-8c74-9a09598c762a'	System	22 Oct 2020 13:42:41
User entered 'None (0)'	System	22 Oct 2020 13:42:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:42:21', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ec1b6545-c2f6-4696-8c74-9a09598c762a'	System	22 Oct 2020 13:42:41
User entered 'None (0)'	System	22 Oct 2020 13:42:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:42:27', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ec1b6545-c2f6-4696-8c74-9a09598c762a'	System	22 Oct 2020 13:42:41
User entered 'None (0)'	System	22 Oct 2020 13:42:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:42:30', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ec1b6545-c2f6-4696-8c74-9a09598c762a'	System	22 Oct 2020 13:42:41
User entered 'None (0)'	System	22 Oct 2020 13:42:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:42:32', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ec1b6545-c2f6-4696-8c74-9a09598c762a'	System	22 Oct 2020 13:42:41
User entered 'None (0)'	System	22 Oct 2020 13:42:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:42:35', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ec1b6545-c2f6-4696-8c74-9a09598c762a'	System	22 Oct 2020 13:42:41
User entered 'No (N)'	System	22 Oct 2020 13:42:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T09:42:38', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'ec1b6545-c2f6-4696-8c74-9a09598c762a'	System	22 Oct 2020 13:42:41
User entered '22 Oct 2020 09:42'	System	22 Oct 2020 13:42:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '21 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '22 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 3'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:14', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1c657333-c9ac-4b2b-9a0f-95a79937008a'	System	23 Oct 2020 02:48:28
User entered 'None (0)'	System	23 Oct 2020 02:48:28

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:16', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1c657333-c9ac-4b2b-9a0f-95a79937008a'	System	23 Oct 2020 02:48:28
User entered 'None (0)'	System	23 Oct 2020 02:48:28

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:17', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1c657333-c9ac-4b2b-9a0f-95a79937008a'	System	23 Oct 2020 02:48:28
User entered 'None (0)'	System	23 Oct 2020 02:48:28

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:18', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1c657333-c9ac-4b2b-9a0f-95a79937008a' User entered 'None (0)'	System	23 Oct 2020 02:48:28
	System	23 Oct 2020 02:48:28

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:20', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1c657333-c9ac-4b2b-9a0f-95a79937008a'	System	23 Oct 2020 02:48:28
User entered 'None (0)'	System	23 Oct 2020 02:48:28

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:21', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1c657333-c9ac-4b2b-9a0f-95a79937008a'	System	23 Oct 2020 02:48:28
User entered 'None (0)'	System	23 Oct 2020 02:48:28

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:23', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1c657333-c9ac-4b2b-9a0f-95a79937008a'	System	23 Oct 2020 02:48:28
User entered 'No (N)'	System	23 Oct 2020 02:48:28

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-22T22:48:26', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '1c657333-c9ac-4b2b-9a0f-95a79937008a' User entered '22 Oct 2020 22:48'	System	23 Oct 2020 02:48:28
	System	23 Oct 2020 02:48:28

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '22 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '23 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 4'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:21', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd2670a1e-aa26-448b-b558-fbc49b9c6eb8'	System	24 Oct 2020 06:46:41
User entered 'None (0)'	System	24 Oct 2020 06:46:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:24', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd2670a1e-aa26-448b-b558-fbc49b9c6eb8'	System	24 Oct 2020 06:46:41
User entered 'None (0)'	System	24 Oct 2020 06:46:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:26', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd2670a1e-aa26-448b-b558-fbc49b9c6eb8'	System	24 Oct 2020 06:46:41
User entered 'None (0)'	System	24 Oct 2020 06:46:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:28', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd2670a1e-aa26-448b-b558-fbc49b9c6eb8'	System	24 Oct 2020 06:46:41
User entered 'None (0)'	System	24 Oct 2020 06:46:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:30', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd2670a1e-aa26-448b-b558-fbc49b9c6eb8'	System	24 Oct 2020 06:46:41
User entered 'None (0)'	System	24 Oct 2020 06:46:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:33', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd2670a1e-aa26-448b-b558-fbc49b9c6eb8'	System	24 Oct 2020 06:46:41
User entered 'None (0)'	System	24 Oct 2020 06:46:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:36', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd2670a1e-aa26-448b-b558-fbc49b9c6eb8'	System	24 Oct 2020 06:46:41
User entered 'No (N)'	System	24 Oct 2020 06:46:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T02:46:40', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'd2670a1e-aa26-448b-b558-fbc49b9c6eb8'	System	24 Oct 2020 06:46:41
User entered '24 Oct 2020 02:46'	System	24 Oct 2020 06:46:41

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '23 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 5'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:39', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4697dcf7-88c8-4491-a348-ddc39049ee2b'	System	25 Oct 2020 00:52:07
User entered 'None (0)'	System	25 Oct 2020 00:52:07

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:41', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4697dcf7-88c8-4491-a348-ddc39049ee2b'	System	25 Oct 2020 00:52:07
User entered 'None (0)'	System	25 Oct 2020 00:52:07

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:43', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4697dcf7-88c8-4491-a348-ddc39049ee2b'	System	25 Oct 2020 00:52:07
User entered 'None (0)'	System	25 Oct 2020 00:52:07

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:46', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4697dcf7-88c8-4491-a348-ddc39049ee2b'	System	25 Oct 2020 00:52:07
User entered 'None (0)'	System	25 Oct 2020 00:52:07

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:52', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4697dcf7-88c8-4491-a348-ddc39049ee2b'	System	25 Oct 2020 00:52:07
User entered 'None (0)'	System	25 Oct 2020 00:52:07

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:51:55', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4697dcf7-88c8-4491-a348-ddc39049ee2b'	System	25 Oct 2020 00:52:07
User entered 'None (0)'	System	25 Oct 2020 00:52:07

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:52:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4697dcf7-88c8-4491-a348-ddc39049ee2b'	System	25 Oct 2020 00:52:07
User entered 'No (N)'	System	25 Oct 2020 00:52:07

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-24T20:52:03', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '4697dcf7-88c8-4491-a348-ddc39049ee2b'	System	25 Oct 2020 00:52:07
User entered '24 Oct 2020 20:52'	System	25 Oct 2020 00:52:07

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '24 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '25 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 6'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:25', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '05a780dc-cd03-4beb-8e55-12b814a92aa5'	System	26 Oct 2020 01:06:42
User entered 'None (0)'	System	26 Oct 2020 01:06:42

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:27', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '05a780dc-cd03-4beb-8e55-12b814a92aa5'	System	26 Oct 2020 01:06:42
User entered 'None (0)'	System	26 Oct 2020 01:06:42

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:29', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '05a780dc-cd03-4beb-8e55-12b814a92aa5'	System	26 Oct 2020 01:06:42
User entered 'None (0)'	System	26 Oct 2020 01:06:42

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:30', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '05a780dc-cd03-4beb-8e55-12b814a92aa5'	System	26 Oct 2020 01:06:42
User entered 'None (0)'	System	26 Oct 2020 01:06:42

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:31', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '05a780dc-cd03-4beb-8e55-12b814a92aa5'	System	26 Oct 2020 01:06:42
User entered 'None (0)'	System	26 Oct 2020 01:06:42

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:33', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '05a780dc-cd03-4beb-8e55-12b814a92aa5'	System	26 Oct 2020 01:06:42
User entered 'None (0)'	System	26 Oct 2020 01:06:42

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:36', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '05a780dc-cd03-4beb-8e55-12b814a92aa5'	System	26 Oct 2020 01:06:42
User entered 'No (N)'	System	26 Oct 2020 01:06:42

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-25T21:06:38', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '05a780dc-cd03-4beb-8e55-12b814a92aa5'	System	26 Oct 2020 01:06:42
User entered '25 Oct 2020 21:06'	System	26 Oct 2020 01:06:42

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '25 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '26 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
Data entry locked.	System	20 Oct 2020 15:01:25
User entered 'Day 7'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:45', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c56b97e0-1bf7-4145-a63d-98da9516a602'	System	27 Oct 2020 01:15:08
User entered 'None (0)'	System	27 Oct 2020 01:15:08

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:47', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c56b97e0-1bf7-4145-a63d-98da9516a602'	System	27 Oct 2020 01:15:08
User entered 'None (0)'	System	27 Oct 2020 01:15:08

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:49', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c56b97e0-1bf7-4145-a63d-98da9516a602'	System	27 Oct 2020 01:15:08
User entered 'None (0)'	System	27 Oct 2020 01:15:08

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:51', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c56b97e0-1bf7-4145-a63d-98da9516a602'	System	27 Oct 2020 01:15:08
User entered 'None (0)'	System	27 Oct 2020 01:15:08

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:53', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c56b97e0-1bf7-4145-a63d-98da9516a602'	System	27 Oct 2020 01:15:08
User entered 'None (0)'	System	27 Oct 2020 01:15:08

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:54', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c56b97e0-1bf7-4145-a63d-98da9516a602'	System	27 Oct 2020 01:15:08
User entered 'None (0)'	System	27 Oct 2020 01:15:08

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

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)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:56', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c56b97e0-1bf7-4145-a63d-98da9516a602'	System	27 Oct 2020 01:15:08
User entered 'No (N)'	System	27 Oct 2020 01:15:08

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de0a2b9208157a56)', Time: '2020-10-26T21:14:58', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c56b97e0-1bf7-4145-a63d-98da9516a602'	System	27 Oct 2020 01:15:08
User entered '26 Oct 2020 21:14'	System	27 Oct 2020 01:15:08

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '26 Oct 2020 12:00'	System	20 Oct 2020 15:01:25

US3632107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:54:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:29:24
User entered '27 Oct 2020 11:59'	System	20 Oct 2020 15:01:25

US3632107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	27 Oct 2020 20:08:24

US3632107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '27 Oct 2020'	Isaac Perez (b) (4)	27 Oct 2020 20:08:24

US3632107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Contact Made (CONTACT MADE)'	Isaac Perez (b) (4)	27 Oct 2020 20:08:24

US3632107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	27 Oct 2020 20:08:24

US3632107

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	27 Oct 2020 20:08:29

US3632107

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'I'	System	27 Oct 2020 20:08:29

US3632107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	10 Nov 2020 17:47:29

US3632107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '3 Nov 2020'	Isaac Perez (b) (4)	10 Nov 2020 17:47:29

US3632107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Contact Made (CONTACT MADE)'	Isaac Perez (b) (4)	10 Nov 2020 17:47:29

US3632107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	10 Nov 2020 17:47:29

US3632107

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	10 Nov 2020 17:47:33

US3632107

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'I'	System	10 Nov 2020 17:47:33

US3632107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	10 Nov 2020 17:47:41

US3632107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '10 Nov 2020'	Isaac Perez (b) (4)	10 Nov 2020 17:47:41

US3632107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Contact Made (CONTACT MADE)'	Isaac Perez (b) (4)	10 Nov 2020 17:47:41

US3632107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	10 Nov 2020 17:47:41

US3632107

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	10 Nov 2020 17:47:45

US3632107

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'I'	System	10 Nov 2020 17:47:45

US3632107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Christina Bacher (b) (4)	17 Nov 2020 14:10:44

US3632107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '17 Nov 2020'	Christina Bacher (b) (4)	17 Nov 2020 14:10:44

US3632107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Clinic (Clinic)'	Christina Bacher (b) (4)	17 Nov 2020 14:10:44

US3632107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'VISIT3'	System	17 Nov 2020 14:10:44

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	Christina Bacher (b) (4)	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Christina Bacher (b) (4)	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Christina Bacher (b) (4)	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered empty.	System	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Christina Bacher (b) (4)	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Christina Bacher (b) (4)	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Christina Bacher (b) (4)	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Christina Bacher (b) (4)	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered empty.	System	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Christina Bacher (b) (4)	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered empty.	System	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Christina Bacher (b) (4)	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered empty.	System	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Christina Bacher (b) (4)	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered empty.	System	17 Nov 2020 14:10:59

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58

US3632107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58

US3632107

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'No (N)'	Christina Bacher (b) (4)	17 Nov 2020 14:11:03

US3632107

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered empty.	Christina Bacher (b) (4)	17 Nov 2020 14:11:03

US3632107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Christina Bacher (b) (4)	17 Nov 2020 14:11:22

US3632107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '17 Nov 2020'	Christina Bacher (b) (4)	17 Nov 2020 14:11:22

US3632107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered '08:46'	Christina Bacher (b) (4)	17 Nov 2020 14:11:22

US3632107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered '17 Nov 2020 08:46'	System	17 Nov 2020 14:11:22

US3632107

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:59
User entered 'Yes (Y)'	Christina Bacher (b) (4)	17 Nov 2020 14:11:25

US3632107

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'I'	System	17 Nov 2020 14:11:25

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2020-11-23T15:12:11', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered 'Yes (Y)'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2020-11-23T15:12:47', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered 'Yes (Y)'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:12:52', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:09', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered 'Yes (Y)'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '1'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '1'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '1'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:13:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '0'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:14:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:14:06', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered 'Yes (Y)'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:14:13', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-23T15:14:18', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '31896d80-a96f-4f8c-bf52-e6cf240ee8a9'	System	23 Nov 2020 20:14:27
User entered '23 Nov 2020 15:14:18'	System	23 Nov 2020 20:14:27

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2020-11-28T10:25:31', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered 'Yes (Y)'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2020-11-28T10:25:46', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered 'Yes (Y)'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:25:50', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:02', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered 'Yes (Y)'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '1'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '1'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '1'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '0'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:45', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:50', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered 'No (N)'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-11-28T10:26:57', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '276be731-434b-43b1-8545-ebdf86489fff'	System	28 Nov 2020 15:27:05
User entered '28 Nov 2020 10:26:57'	System	28 Nov 2020 15:27:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2020-12-05T11:05:33', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '7420400b-370c-440e-b28b-9cb7bf965906'	System	05 Dec 2020 16:05:59
User entered 'No (N)'	System	05 Dec 2020 16:05:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2020-12-05T11:05:40', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '7420400b-370c-440e-b28b-9cb7bf965906'	System	05 Dec 2020 16:05:59
User entered 'Yes (Y)'	System	05 Dec 2020 16:05:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-12-05T11:05:43', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '7420400b-370c-440e-b28b-9cb7bf965906'	System	05 Dec 2020 16:05:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 16:05:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-12-05T11:05:47', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '7420400b-370c-440e-b28b-9cb7bf965906'	System	05 Dec 2020 16:05:59
User entered '05 Dec 2020 11:05:47'	System	05 Dec 2020 16:05:59

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2020-12-15T15:45:21', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'acdcde29-6168-4985-b620-78590438f776'	System	15 Dec 2020 20:45:34
User entered 'No (N)'	System	15 Dec 2020 20:45:34

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2020-12-15T15:45:25', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'acdcde29-6168-4985-b620-78590438f776'	System	15 Dec 2020 20:45:34
User entered 'No (N)'	System	15 Dec 2020 20:45:34

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-12-15T15:45:28', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'acdcde29-6168-4985-b620-78590438f776'	System	15 Dec 2020 20:45:34
User entered '15 Dec 2020 15:45:28'	System	15 Dec 2020 20:45:34

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2020-12-23T16:54:47', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '28d1378e-2773-4701-be57-2af95f89770c'	System	23 Dec 2020 21:55:06
User entered 'No (N)'	System	23 Dec 2020 21:55:06

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2020-12-23T16:54:56', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '28d1378e-2773-4701-be57-2af95f89770c'	System	23 Dec 2020 21:55:06
User entered 'No (N)'	System	23 Dec 2020 21:55:06

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-12-23T16:55:04', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '28d1378e-2773-4701-be57-2af95f89770c'	System	23 Dec 2020 21:55:06
User entered '23 Dec 2020 16:55:04'	System	23 Dec 2020 21:55:06

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2020-12-29T09:39:56', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c4ef64d8-c513-4f41-86d1-497b951a0c56'	System	29 Dec 2020 14:40:15
User entered 'No (N)'	System	29 Dec 2020 14:40:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2020-12-29T09:40:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c4ef64d8-c513-4f41-86d1-497b951a0c56'	System	29 Dec 2020 14:40:15
User entered 'No (N)'	System	29 Dec 2020 14:40:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2020-12-29T09:40:12', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c4ef64d8-c513-4f41-86d1-497b951a0c56'	System	29 Dec 2020 14:40:15
User entered '29 Dec 2020 09:40:12'	System	29 Dec 2020 14:40:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-01-02T00:23:42', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'eecbd6bc-df09-4939-9f38-366bea177344'	System	02 Jan 2021 05:23:56
User entered 'No (N)'	System	02 Jan 2021 05:23:56

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-01-02T00:23:49', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'eecbd6bc-df09-4939-9f38-366bea177344'	System	02 Jan 2021 05:23:56
User entered 'No (N)'	System	02 Jan 2021 05:23:56

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-01-02T00:23:53', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'eecbd6bc-df09-4939-9f38-366bea177344'	System	02 Jan 2021 05:23:56
User entered '02 Jan 2021 00:23:53'	System	02 Jan 2021 05:23:56

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-01-09T17:18:11', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'e8c8b58d-c7b5-4a35-8929-6078d5bd4bfa'	System	09 Jan 2021 22:18:22
User entered 'No (N)'	System	09 Jan 2021 22:18:22

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-01-09T17:18:14', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'e8c8b58d-c7b5-4a35-8929-6078d5bd4bfa'	System	09 Jan 2021 22:18:22
User entered 'No (N)'	System	09 Jan 2021 22:18:22

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-01-09T17:18:17', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'e8c8b58d-c7b5-4a35-8929-6078d5bd4bfa' User entered '09 Jan 2021 17:18:17'	System	09 Jan 2021 22:18:22
	System	09 Jan 2021 22:18:22

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-01-17T22:54:01', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '71b29449-0230-401e-b363-d6f8104d04f6'	System	18 Jan 2021 03:54:10
User entered 'No (N)'	System	18 Jan 2021 03:54:10

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-01-17T22:54:03', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '71b29449-0230-401e-b363-d6f8104d04f6'	System	18 Jan 2021 03:54:10
User entered 'No (N)'	System	18 Jan 2021 03:54:10

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-01-17T22:54:06', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '71b29449-0230-401e-b363-d6f8104d04f6'	System	18 Jan 2021 03:54:10
User entered '17 Jan 2021 22:54:06'	System	18 Jan 2021 03:54:10

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-01-27T11:42:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '655c3e30-ba1d-49be-8e1a-d7d2157a11ae'	System	27 Jan 2021 16:42:08
User entered 'No (N)'	System	27 Jan 2021 16:42:08

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-01-27T11:42:01', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '655c3e30-ba1d-49be-8e1a-d7d2157a11ae'	System	27 Jan 2021 16:42:08
User entered 'No (N)'	System	27 Jan 2021 16:42:08

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-01-27T11:42:04', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '655c3e30-ba1d-49be-8e1a-d7d2157a11ae' User entered '27 Jan 2021 11:42:04'	System	27 Jan 2021 16:42:08
	System	27 Jan 2021 16:42:08

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-02-01T12:08:50', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '23ffef48-c048-4c91-acf3-37bd46f6e7b3'	System	01 Feb 2021 17:11:51
User entered 'No (N)'	System	01 Feb 2021 17:11:51

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-02-01T12:08:52', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '23ffef48-c048-4c91-acf3-37bd46f6e7b3'	System	01 Feb 2021 17:11:51
User entered 'No (N)'	System	01 Feb 2021 17:11:51

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-02-01T12:08:55', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '23ffef48-c048-4c91-acf3-37bd46f6e7b3'	System	01 Feb 2021 17:11:51
User entered '01 Feb 2021 12:08:55'	System	01 Feb 2021 17:11:51

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-02-10T08:35:03', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'aa2d2b0e-b830-44dc-af3b-d585a11dd8df'	System	10 Feb 2021 13:35:14
User entered 'No (N)'	System	10 Feb 2021 13:35:14

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-02-10T08:35:06', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'aa2d2b0e-b830-44dc-af3b-d585a11dd8df'	System	10 Feb 2021 13:35:14
User entered 'No (N)'	System	10 Feb 2021 13:35:14

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-02-10T08:35:11', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'aa2d2b0e-b830-44dc-af3b-d585a11dd8df'	System	10 Feb 2021 13:35:14
User entered '10 Feb 2021 08:35:11'	System	10 Feb 2021 13:35:14

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-02-13T09:42:23', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9ed4b0ef-ef94-448c-a91c-1fbb81b89a97'	System	13 Feb 2021 14:42:31
User entered 'No (N)'	System	13 Feb 2021 14:42:31

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-02-13T09:42:25', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9ed4b0ef-ef94-448c-a91c-1fbb81b89a97'	System	13 Feb 2021 14:42:31
User entered 'No (N)'	System	13 Feb 2021 14:42:31

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-02-13T09:42:29', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9ed4b0ef-ef94-448c-a91c-1fbb81b89a97'	System	13 Feb 2021 14:42:31
User entered '13 Feb 2021 09:42:29'	System	13 Feb 2021 14:42:31

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-02-22T22:17:45', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '08488a17-3c5f-4f96-9f9e-b1df78201a86'	System	23 Feb 2021 03:18:19
User entered 'No (N)'	System	23 Feb 2021 03:18:19

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-02-22T22:17:55', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '08488a17-3c5f-4f96-9f9e-b1df78201a86'	System	23 Feb 2021 03:18:19
User entered 'No (N)'	System	23 Feb 2021 03:18:19

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-02-22T22:18:15', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '08488a17-3c5f-4f96-9f9e-b1df78201a86'	System	23 Feb 2021 03:18:19
User entered '22 Feb 2021 22:18:15'	System	23 Feb 2021 03:18:19

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-03-02T01:16:28-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '90095881-6c2e-4b12-a7e2-90de83778edd'	System	02 Mar 2021 06:17:16
User entered 'No (N)'	System	02 Mar 2021 06:17:16

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-03-02T01:16:53-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '90095881-6c2e-4b12-a7e2-90de83778edd'	System	02 Mar 2021 06:17:16
User entered 'Yes (Y)'	System	02 Mar 2021 06:17:16

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-03-02T01:17:01-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '90095881-6c2e-4b12-a7e2-90de83778edd'	System	02 Mar 2021 06:17:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Mar 2021 06:17:16

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-03-02T01:17:05-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '90095881-6c2e-4b12-a7e2-90de83778edd'	System	02 Mar 2021 06:17:16
User entered '02 Mar 2021 01:17:05'	System	02 Mar 2021 06:17:16

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-03-06T12:22:00-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0c1a1be3-b38e-44c3-af98-4acfaae16a8e'	System	06 Mar 2021 17:22:26
User entered 'No (N)'	System	06 Mar 2021 17:22:26

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-03-06T12:22:07-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0c1a1be3-b38e-44c3-af98-4acfaae16a8e'	System	06 Mar 2021 17:22:26
User entered 'No (N)'	System	06 Mar 2021 17:22:26

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-03-06T12:22:12-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0c1a1be3-b38e-44c3-af98-4acfaae16a8e'	System	06 Mar 2021 17:22:26
User entered '06 Mar 2021 12:22:12'	System	06 Mar 2021 17:22:26

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-03-13T11:54:20-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '8f4632cd-20ab-4fc4-8ac1-bd618ed328ed' User entered 'No (N)'	System	13 Mar 2021 16:54:30
	System	13 Mar 2021 16:54:30

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-03-13T11:54:23-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '8f4632cd-20ab-4fc4-8ac1-bd618ed328ed'	System	13 Mar 2021 16:54:30
User entered 'No (N)'	System	13 Mar 2021 16:54:30

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-03-13T11:54:26-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '8f4632cd-20ab-4fc4-8ac1-bd618ed328ed'	System	13 Mar 2021 16:54:30
User entered '13 Mar 2021 11:54:26'	System	13 Mar 2021 16:54:30

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-03-24T10:47:30-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '20767308-a345-4613-9a77-3c804fa17981'	System	24 Mar 2021 15:47:41
User entered 'No (N)'	System	24 Mar 2021 15:47:41

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-03-24T10:47:35-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '20767308-a345-4613-9a77-3c804fa17981'	System	24 Mar 2021 15:47:41
User entered 'No (N)'	System	24 Mar 2021 15:47:41

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-03-24T10:47:38-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '20767308-a345-4613-9a77-3c804fa17981'	System	24 Mar 2021 15:47:41
User entered '24 Mar 2021 10:47:38'	System	24 Mar 2021 15:47:41

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-03-31T10:50:09-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c9ebbfdb-65a7-44e8-b65d-0b395dda1dd7'	System	31 Mar 2021 14:50:18
User entered 'No (N)'	System	31 Mar 2021 14:50:18

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-03-31T10:50:12-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c9ebbfdb-65a7-44e8-b65d-0b395dda1dd7'	System	31 Mar 2021 14:50:18
User entered 'No (N)'	System	31 Mar 2021 14:50:18

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-03-31T10:50:15-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'c9ebbfdb-65a7-44e8-b65d-0b395dda1dd7' User entered '31 Mar 2021 10:50:15'	System	31 Mar 2021 14:50:18

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-04-05T15:44:29-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'fa6fb013-d5d2-4c24-88ed-6cbc51ad98ed'	System	05 Apr 2021 19:44:40
User entered 'No (N)'	System	05 Apr 2021 19:44:40

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-04-05T15:44:32-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'fa6fb013-d5d2-4c24-88ed-6cbc51ad98ed'	System	05 Apr 2021 19:44:40
User entered 'No (N)'	System	05 Apr 2021 19:44:40

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-04-05T15:44:36-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'fa6fb013-d5d2-4c24-88ed-6cbc51ad98ed'	System	05 Apr 2021 19:44:40
User entered '05 Apr 2021 15:44:36'	System	05 Apr 2021 19:44:40

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-04-13T01:00:04-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '66d2885b-ded9-42e1-b287-75c535946e84'	System	13 Apr 2021 05:00:17
User entered 'No (N)'	System	13 Apr 2021 05:00:17

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-04-13T01:00:09-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '66d2885b-ded9-42e1-b287-75c535946e84'	System	13 Apr 2021 05:00:17
User entered 'No (N)'	System	13 Apr 2021 05:00:17

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-04-13T01:00:12-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '66d2885b-ded9-42e1-b287-75c535946e84'	System	13 Apr 2021 05:00:17
User entered '13 Apr 2021 01:00:12'	System	13 Apr 2021 05:00:17

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-04-19T10:03:29-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'cb218f6c-c4f5-4602-8a67-aef10a7b3961'	System	19 Apr 2021 14:03:41
User entered 'No (N)'	System	19 Apr 2021 14:03:41

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-04-19T10:03:33-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'cb218f6c-c4f5-4602-8a67-aef10a7b3961'	System	19 Apr 2021 14:03:41
User entered 'No (N)'	System	19 Apr 2021 14:03:41

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-04-19T10:03:36-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: 'cb218f6c-c4f5-4602-8a67-aef10a7b3961'	System	19 Apr 2021 14:03:41
User entered '19 Apr 2021 10:03:36'	System	19 Apr 2021 14:03:41

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-04-24T11:07:35-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9a3529dc-7e13-490c-9f43-c1fc8f5c2e03'	System	24 Apr 2021 15:07:46
User entered 'No (N)'	System	24 Apr 2021 15:07:46

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-04-24T11:07:37-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9a3529dc-7e13-490c-9f43-c1fc8f5c2e03'	System	24 Apr 2021 15:07:46
User entered 'No (N)'	System	24 Apr 2021 15:07:46

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-04-24T11:07:41-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '9a3529dc-7e13-490c-9f43-c1fc8f5c2e03' User entered '24 Apr 2021 11:07:41'	System	24 Apr 2021 15:07:46
	System	24 Apr 2021 15:07:46

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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 (37335097e0c04124)', Time: '2021-05-03T10:13:27-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered 'Yes (Y)'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

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 (37335097e0c04124)', Time: '2021-05-03T10:13:37-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered 'No (N)'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:13:46-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered 'Yes (Y)'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '1'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '1'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '1'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:08-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '0'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:10-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:14:47-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered 'No (N)'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-05-03T10:15:01-04:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '0f35889c-f314-46f7-a696-f03237b8505d'	System	03 May 2021 14:15:15
User entered '03 May 2021 10:15:01'	System	03 May 2021 14:15:15

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 10:34:05

US3632107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:54:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:34:05
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 10:34:05

US3632107

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:54:03

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 19:44:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-03-02T01:17:15-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '16fcc5d0-1312-4973-a96b-317270c24048'	System	02 Mar 2021 06:17:21
User entered 'No (N)'	System	02 Mar 2021 06:17:21

US3632107

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:54:03

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:44:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37335097e0c04124)', Time: '2021-03-02T01:17:17-05:00', User OID: 'PatientReportedOutcome (US3632107)', ODM File OID: '16fcc5d0-1312-4973-a96b-317270c24048'	System	02 Mar 2021 06:17:21
User entered '02 Mar 2021 01:17:17'	System	02 Mar 2021 06:17:21

US3632107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	15 Dec 2020 20:47:55

US3632107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '15 Dec 2020'	Christina Bacher (b) (4)	15 Dec 2020 20:47:55

US3632107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Contact Made (CONTACT MADE)'	Christina Bacher (b) (4)	15 Dec 2020 20:47:55

US3632107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	15 Dec 2020 20:47:55

US3632107

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 15:31:30

US3632107

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:30:58
User entered 'I'	System	13 Jan 2021 15:31:30

US3632107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 16:43:24

US3632107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '19 Jan 2021' reason for change: Data Entry Error	Sarah Wiatrek (b) (4)	16 Feb 2021 19:04:16
User entered '18 Jan 2021'	(b) (4), (b) (6)	16 Feb 2021 16:43:24

US3632107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Feb 2021 16:43:24

US3632107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 16:43:24

US3632107

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 16:43:27

US3632107

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User entered 'I'	System	16 Feb 2021 16:43:27

US3632107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Yes (Y)'	Kelly Likos (b) (4)	12 Mar 2021 18:16:01

US3632107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '17 Feb 2021'	Kelly Likos (b) (4)	12 Mar 2021 18:16:01

US3632107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Contact Made (CONTACT MADE)'	Kelly Likos (b) (4)	12 Mar 2021 18:16:01

US3632107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	(b) (4) Kelly Likos (b) (4) (b) (4)	12 Mar 2021 18:16:01

US3632107

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Yes (Y)'	Kelly Likos (b) (4)	12 Mar 2021 18:16:05

US3632107

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User entered 'I'	System	12 Mar 2021 18:16:05

US3632107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Yes (Y)'	Christina Bacher (b) (4)	22 Mar 2021 17:27:47

US3632107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '22 Mar 2021'	Christina Bacher (b) (4)	22 Mar 2021 17:27:47

US3632107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Contact Made (CONTACT MADE)'	Christina Bacher (b) (4)	22 Mar 2021 17:27:47

US3632107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	Christina Bacher (b) (4)	22 Mar 2021 17:27:47

US3632107

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Yes (Y)'	Christina Bacher (b) (4)	22 Mar 2021 17:27:52

US3632107

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:42:42
User entered 'I'	System	22 Mar 2021 17:27:52

US3632107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
	(b) (4)	
User entered 'Yes (Y)'	Christina Bacher (b) (4)	21 Apr 2021 15:13:48
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
	(b) (4)	
User entered '21 Apr 2021'	Christina Bacher (b) (4)	21 Apr 2021 15:13:48
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered 'Clinic (Clinic)'	(b) (4) Christina Bacher (b) (4)	21 Apr 2021 15:13:48

US3632107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	21 Apr 2021 15:13:48

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered 'No (N)'	(b) (4) Christina Bacher (b) (4)	21 Apr 2021 15:13:55
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered empty.	(b) (4)	
	Christina Bacher (b) (4)	21 Apr 2021 15:13:55
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered empty.	(b) (4) Christina Bacher (b) (4)	21 Apr 2021 15:13:55
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 15:13:55

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered empty.	(b) (4)	
	Christina Bacher (b) (4)	21 Apr 2021 15:13:55
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered empty.	(b) (4) Christina Bacher (b) (4)	21 Apr 2021 15:13:55
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered empty.	(b) (4) Christina Bacher (b) (4)	21 Apr 2021 15:13:55
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered empty.	(b) (4) Christina Bacher (b) (4)	21 Apr 2021 15:13:55
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 15:13:55

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered empty.	(b) (4) Christina Bacher (b) (4)	21 Apr 2021 15:13:55
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 15:13:55

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered empty.	(b) (4) Christina Bacher (b) (4)	21 Apr 2021 15:13:55
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 15:13:55

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered empty.	(b) (4) Christina Bacher (b) (4)	21 Apr 2021 15:13:55
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 15:13:55

US3632107

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered 'No (N)'	(b) (4) Christina Bacher (b) (4)	21 Apr 2021 15:13:59

US3632107

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
	(b) (4)	
User entered empty.	Christina Bacher (b) (4)	21 Apr 2021 15:13:59
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered 'Yes (Y)'	(b) (4) Christina Bacher (b) (4)	21 Apr 2021 15:14:16

US3632107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
User entered '21 Apr 2021'	(b) (4) Christina Bacher (b) (4)	21 Apr 2021 15:14:16
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
	(b) (4)	
User entered '10:25'	Christina Bacher (b) (4)	21 Apr 2021 15:14:16
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '21 Apr 2021 10:25'	System	21 Apr 2021 15:14:16

US3632107

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
	(b) (4)	
User entered 'Yes (Y)'	Christina Bacher (b) (4)	21 Apr 2021 15:14:18
	(b) (4)	

US3632107

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 15:14:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:54:03

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Please complete severity assessment as expected.' (Site from CRA).	(b) (4)	
Query 'Please complete severity assessment as expected.' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:51:54
DataPoint Verified.	Christina Bacher (b) (4)	04 Dec 2020 15:18:54
	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:31:24
	(b) (4), (b) (6)	03 Dec 2020 01:59:42
User opened query 'Please complete severity assessment as expected.' (Site from CRA).		
User entered '23 Nov 2020'	Christina Bacher (b) (4)	24 Nov 2020 16:28:38
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:54:03

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:31:56
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:33:05
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:31:24
User entered '12:00'	Christina Bacher (b) (4)	24 Nov 2020 16:28:38
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:54:03

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:04
User entered '23 Nov 2020 12:00'	System	24 Nov 2020 16:28:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:54:03

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:31:24
User entered 'Safety Call (Safety Call)'	Christina Bacher (b) (4)	24 Nov 2020 16:28:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:54:03

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:31:24
User entered 'Yes (Y)'	Christina Bacher (b) (4)	24 Nov 2020 16:28:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 1 (Day 1)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '17 Nov 2020'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4) (b) (4)	24 Nov 2020 16:32:51

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	24 Nov 2020 16:32:51

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4)	24 Nov 2020 16:32:51

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:32:51
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 2 (Day 2)' reason for change:	(b) (4)	
Data Entry Error	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
User entered 'Day 18 (Day 18)'	(b) (4)	
	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '18 Nov 2020'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4)	24 Nov 2020 16:33:59

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	24 Nov 2020 16:33:59

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
User entered 'None (None)'	(b) (4)	
	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4) (b) (4)	24 Nov 2020 16:33:59

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:33:59
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 3 (Day 3)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '19 Nov 2020'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4)	24 Nov 2020 16:38:13

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	24 Nov 2020 16:38:13

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:38:13

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 4 (Day 4)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '20 Nov 2020'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4)	24 Nov 2020 16:39:20

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	24 Nov 2020 16:39:20

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4) (b) (4)	24 Nov 2020 16:39:20

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Severe (Severe)' reason for change:	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
Data Entry Error	(b) (4)	
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:39:20
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 5 (Day 5)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '21 Nov 2020'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	24 Nov 2020 16:40:16

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Severe (Severe)' reason for change:	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
Data Entry Error	(b) (4)	
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:40:16
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 6 (Day 6)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '22 Nov 2020'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4) (b) (4)	24 Nov 2020 16:41:17

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	24 Nov 2020 16:41:17

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4) (b) (4)	24 Nov 2020 16:41:17

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
User entered 'None (None)'	(b) (4)	
	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Severe (Severe)' reason for change:	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
Data Entry Error	(b) (4)	
User entered 'Moderate (Moderate)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:52:23
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:36:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:44:48
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 13:39:36
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 13:39:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 13:39:36
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:41:17
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 7 (Day 7)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '23 Nov 2020'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4) (b) (4)	24 Nov 2020 16:43:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	24 Nov 2020 16:43:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4) (b) (4)	24 Nov 2020 16:43:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	17 Dec 2020 21:47:03
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:59:07
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:47:03
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:59:12
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:59:13
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	17 Dec 2020 21:47:03
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Severe (Severe)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:52:49
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:36:21
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 13:39:36
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 13:39:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 13:39:36
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 17:59:18
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:43:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 8 (Day 8)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '24 Nov 2020'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	17 Dec 2020 21:47:03
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 18:37:26
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered '100' reason for change: Data Entry Error	Christina Bacher (b) (4)	04 Dec 2020 15:15:17
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 18:37:30
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4)	24 Nov 2020 16:49:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	24 Nov 2020 16:49:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered '97.9' F reason for change: Data Entry Error	Christina Bacher (b) (4)	04 Dec 2020 15:15:17
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 18:37:32
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered missing code ND - Not Done.	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Severe (Severe)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	24 Nov 2020 16:49:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 9 (Day 9)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '25 Nov 2020'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '98'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	25 Nov 2020 17:33:36

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '97.9' F	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	25 Nov 2020 17:33:36

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 11 (Day 11)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '27 Nov 2020'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '97'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	30 Nov 2020 01:10:14

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '97.3' F	Christina Bacher (b) (4)	30 Nov 2020 01:10:14
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:10:14

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 12 (Day 12)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '28 Nov 2020'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '98'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '98.1' F	Christina Bacher (b) (4)	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:12:40

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 13 (Day 13)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '29 Nov 2020'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '98'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '97.3' F	Christina Bacher (b) (4)	30 Nov 2020 01:13:48
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
User entered 'None (None)'	(b) (4) Christina Bacher (b) (4)	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 01:13:48

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 14 (Day 14)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '30 Nov 2020'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '97'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	30 Nov 2020 20:55:44

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '96.9' F	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	30 Nov 2020 20:55:44

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 15 (Day 15)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '1 Dec 2020'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '96'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '96.9' F	Christina Bacher (b) (4)	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4) (b) (4)	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	01 Dec 2020 20:40:37

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 16 (Day 16)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '2 Dec 2020'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '0'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '98'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	02 Dec 2020 19:56:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered '98.2' F	Christina Bacher (b) (4)	02 Dec 2020 19:56:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:53:20
User entered 'None (None)'	Christina Bacher (b) (4)	02 Dec 2020 19:56:00
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 17 (Day 17)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:35:50
User entered '3 Dec 2020'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:35:52
User entered '0'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:35:57
User entered '97'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	03 Dec 2020 20:23:26

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:36:00
User entered '97.3' F	Christina Bacher (b) (4)	03 Dec 2020 20:23:26

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:36:04
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:36:06
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:36:10
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:36:13
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:36:15
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:36:24
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:36:26
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:36:27
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:36:29
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:36:31
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:36:32
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:36:34
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:36:36
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:36:37
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:36:39
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:36:40
User entered 'None (None)'	Christina Bacher (b) (4)	03 Dec 2020 20:23:26
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 18 (Day 18)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:37:37
User entered '4 Dec 2020'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:37:38
User entered '0'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:37:40
User entered '97'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:37:42
User entered '98.1' F	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:37:44
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:37:47
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:37:49
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:37:51
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:37:55
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:37:56
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:37:58
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:37:59
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:38:00
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:38:03
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:38:05
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:38:06
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:38:09
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:38:14
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:38:12
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:38:15
User entered 'None (None)'	Christina Bacher (b) (4)	04 Dec 2020 20:30:50

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 19 (Day 19)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:38:43
User entered '5 Dec 2020'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:38:47
User entered '0'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	17 Dec 2020 21:38:49
User entered '89'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	06 Dec 2020 00:02:45

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:38:51
User entered '98.1' F	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:39:01
User entered 'None (None)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:39:03
User entered 'None (None)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:39:04
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:39:09
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:39:12
User entered 'None (None)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:39:18
User entered 'None (None)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	17 Dec 2020 21:39:20
User entered 'None (None)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:39:22
User entered 'None (None)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:39:24
User entered 'None (None)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:39:25
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:39:28
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:39:29
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:39:34
User entered 'None (None)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:39:36
User entered 'None (None)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:40:10
User entered 'None (None)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:40:12
User entered 'None (None)'	Christina Bacher (b) (4)	06 Dec 2020 00:02:45

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 20 (Day 20)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:40:38
User entered '6 Dec 2020'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:40:40
User entered '0'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:40:42
User entered '97'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:40:44
User entered '97.5' F	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:40:46
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:40:48
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	17 Dec 2020 21:40:51
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:40:52
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	17 Dec 2020 21:40:57
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:40:58
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:41:00
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:41:02
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:41:06
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:41:09
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:41:12
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:41:13
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:41:15
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:41:17
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:41:18
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:41:20
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 13:54:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User closed query 'Per CDM: Both Log Line #20 and Log Line #21 have been labeled as Day 21. Please reconcile and update appropriately.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:26:48
Query 'Per CDM: Both Log Line #20 and Log Line #21 have been labeled as Day 21. Please reconcile and update appropriately.' answered with 'updated' (Site from DM).	Christina Bacher (b) (4) (b) (4)	22 Mar 2021 17:31:31
User opened query 'Per CDM: Both Log Line #20 and Log Line #21 have been labeled as Day 21. Please reconcile and update appropriately.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:30:18
User signature succeeded.	Colleen Kelley (b) (4) (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 21 (Day 21)'	Christina Bacher (b) (4) (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:41:40
User entered '7 Dec 2020'	Christina Bacher (b) (4) (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:41:43
User entered '0'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:41:45
User entered '98'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:41:47
User entered '97.6' F	Christina Bacher (b) (4)	07 Dec 2020 20:18:38
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:41:49
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:41:51
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:41:53
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:41:54
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:41:56
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:42:01
User entered 'None (None)'	Christina Bacher (b) (4) (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:02
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:04
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:06
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:08
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	17 Dec 2020 21:42:09
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:11
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:13
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:15
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:42:17
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:18
User entered 'None (None)'	Christina Bacher (b) (4)	07 Dec 2020 20:18:38

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
Signature has been broken.	Christina Bacher (b) (4)	22 Mar 2021 17:30:13
User entered 'Day 22 (Day 22)' reason for change:	Christina Bacher (b) (4)	22 Mar 2021 17:30:13
Data Entry Error	(b) (4)	
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 21 (Day 21)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:41
User entered '8 Dec 2020'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:43
User entered '0'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	17 Dec 2020 21:42:45
User entered '98'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:47
User entered '97.6' F	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:50
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:51
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:42:53
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:42:55
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:42:57
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:42:58
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:43:04
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:43:10
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:43:07
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:43:11
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:43:14
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:43:15
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:43:18
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:43:20
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:43:22
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:43:24
User entered 'None (None)'	Christina Bacher (b) (4)	08 Dec 2020 21:02:33

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
Signature has been broken.	Christina Bacher (b) (4)	22 Mar 2021 17:30:13
User entered 'Day 23 (Day 23)' reason for change:	Christina Bacher (b) (4)	22 Mar 2021 17:30:13
Data Entry Error	(b) (4)	
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 22 (Day 22)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:43:44
User entered '9 Dec 2020'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:43:46
User entered '0'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:43:51
User entered '97'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	11 Dec 2020 18:43:54

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:43:54
User entered '98.1' F	Christina Bacher (b) (4)	11 Dec 2020 18:43:54
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:43:57
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	17 Dec 2020 21:43:59
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:44:05
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:44:08
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:44:10
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:44:12
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:44:14
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:44:16
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:44:19
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:44:20
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:44:22
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:44:24
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:44:26
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:44:29
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:44:31
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:44:32
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:43:54

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
Signature has been broken.	Christina Bacher (b) (4)	22 Mar 2021 17:30:13
User entered 'Day 24 (Day 24)' reason for change:	Christina Bacher (b) (4)	22 Mar 2021 17:30:13
Data Entry Error	(b) (4)	
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 23 (Day 23)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:44:53
User entered '10 Dec 2020'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:44:54
User entered '0'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:44:56
User entered '96'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:44:58
User entered '98.3' F	Christina Bacher (b) (4)	11 Dec 2020 18:44:47
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:00
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:10
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:11
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:13
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:45:15
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:16
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:18
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:20
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	17 Dec 2020 21:45:21
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:23
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:45:25
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:26
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:28
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:45:29
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:45:31
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:33
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 18:44:47

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
Signature has been broken.	Christina Bacher (b) (4)	22 Mar 2021 17:30:13
User entered 'Day 25 (Day 25)' reason for change:	Christina Bacher (b) (4)	22 Mar 2021 17:30:13
Data Entry Error	(b) (4)	
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 24 (Day 24)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:45:53
User entered '11 Dec 2020'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:54
User entered '0'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:56
User entered '98'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:58
User entered '97.1' F	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:45:59
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:46:01
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:46:03
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:46:04
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:46:06
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:46:08
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:46:09
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:46:12
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:46:11
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:46:15
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:46:23
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:46:17
User entered 'Mild (Mild)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:46:19
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:46:21
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:46:26
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:46:27
User entered 'None (None)'	Christina Bacher (b) (4)	11 Dec 2020 20:15:18
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Day 26 (Day 26)' reason for change: Data Entry Error	Christina Bacher (b) (4)	22 Mar 2021 17:30:13
User entered 'Day 25 (Day 25)' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Feb 2021 19:17:45
Signature has been broken.	Aastha KC (b) (4)	22 Feb 2021 19:17:08
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Feb 2021 19:17:08
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Day 25 (Day 25)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User closed query 'Per ETRTR: Since Symptoms are resolved on 12Dec20, please consider updating AE page to for End Date to reflect 12Dec20 instead of 21Dec20 if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 23:36:21
Query 'Per ETRTR: Since Symptoms are resolved on 12Dec20, please consider updating AE page to for End Date to reflect 12Dec20 instead of 21Dec20 if applicable, thanks.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 17:17:53
User opened query 'Per ETRTR: Since Symptoms are resolved on 12Dec20, please consider updating AE page to for End Date to reflect 12Dec20 instead of 21Dec20 if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 16:55:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered '12 Dec 2020'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered '0'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered '99'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User entered '%'	System	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered '98.1' F	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:54:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:47:03
User entered 'None (None)'	Christina Bacher (b) (4)	14 Dec 2020 20:17:55

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:03

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 19:01:44
User entered '24 Nov 2020'	Christina Bacher (b) (4)	30 Nov 2020 19:05:09
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:03

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:01:44
User entered 'Yes (Y)'	Christina Bacher (b) (4)	30 Nov 2020 19:05:09

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:03

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:01:44
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)	02 Dec 2020 15:54:44
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 'Yes. They tested positive. AEs updated' (Site from System).	Christina Bacher (b) (4)	30 Nov 2020 20:56:13
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	30 Nov 2020 19:05:09
User entered 'Yes (Y)'	Christina Bacher (b) (4)	30 Nov 2020 19:05:09

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:03

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:01:44
User entered '24 Nov 2020'	Christina Bacher (b) (4)	30 Nov 2020 19:05:09

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:03

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:01:44
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 19:05:09

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:03

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:01:44
User entered empty.	Christina Bacher (b) (4)	30 Nov 2020 19:05:09

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:03

[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)	03 May 2021 23:33:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:01:44
User entered 'No (N)'	Christina Bacher (b) (4)	30 Nov 2020 19:05:09

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:03

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:01:44
User entered empty.	Christina Bacher (b) (4)	30 Nov 2020 19:05:09

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:03

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:01:44
User entered empty.	Christina Bacher (b) (4)	30 Nov 2020 19:05:09

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:54:03

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:33:21
User entered 'I'	System	30 Nov 2020 19:05:09

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:48:09
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:18:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:18:16
User entered 'No (N)' reason for change: Per Query Resolution	Christina Bacher (b) (4) (b) (4)	04 Dec 2020 15:18:16
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:17:42
User entered empty.	Christina Bacher (b) (4) (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:24
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty; reason for change New Information	(b) (4)	
	Christina Bacher (b) (4)	21 Jan 2021 21:41:59
DataPoint Un-verified.	(b) (4)	
	Christina Bacher (b) (4)	21 Jan 2021 21:34:45
User entered '05 Dec 2020' reason for change: New Information	(b) (4)	
	Christina Bacher (b) (4)	21 Jan 2021 21:34:45
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:53:28
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty; reason for change New Information	(b) (4)	
	Christina Bacher (b) (4)	21 Jan 2021 21:41:59
DataPoint Un-verified.	(b) (4)	
	Christina Bacher (b) (4)	21 Jan 2021 21:38:12
User entered '05 Dec 2020' reason for change: New Information	(b) (4)	
	Christina Bacher (b) (4)	21 Jan 2021 21:38:12
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

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)	03 May 2021 23:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:18
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Un-verified.	(b) (4)	
	Christina Bacher (b) (4)	21 Jan 2021 21:33:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Christina Bacher (b) (4)	21 Jan 2021 21:33:20
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:18:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:18:16
User entered 'No (N)' reason for change: Data Entry Error	Christina Bacher (b) (4)	04 Dec 2020 15:18:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:17:42
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:01
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Un-verified.	(b) (4) Christina Bacher (b) (4)	21 Jan 2021 21:41:59
User entered '05 Dec 2020' reason for change: New Information	(b) (4) Christina Bacher (b) (4)	21 Jan 2021 21:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4) (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:04
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Un-verified.	(b) (4)	
	Christina Bacher (b) (4)	21 Jan 2021 21:41:59
User entered '05 Dec 2020' reason for change: New Information	(b) (4)	21 Jan 2021 21:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:55:06
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User closed query 'Per ETRTR: Please add Oxygen saturation reported on 05Dec20, thanks.' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 23:35:17
Query 'Per ETRTR: Please add Oxygen saturation reported on 05Dec20, thanks.' answered with 'added' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 17:15:47
DataPoint Un-verified.	(b) (4), (b) (6)	10 Mar 2021 17:15:36
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 17:15:36
User entered '89' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 17:15:36
User opened query 'Per ETRTR: Please add Oxygen saturation reported on 05Dec20, thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 16:56:50
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:48:09
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:18:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:18:16
User entered 'No (N)' reason for change: Data Entry Error	Christina Bacher (b) (4) (b) (4)	04 Dec 2020 15:18:16
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:17:42
User entered empty.	Christina Bacher (b) (4) (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered 'No (N)'	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:48:09
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:18:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 15:18:16
User entered 'No (N)' reason for change: Data Entry Error	Christina Bacher (b) (4) (b) (4)	04 Dec 2020 15:18:16
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 15:17:42
User entered empty.	Christina Bacher (b) (4) (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42
	(b) (4)	

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections and update accordingly as it appears some responses are missing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 05:21:09
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections and update accordingly as it appears some responses are missing. ' answered with 'Reviewed and updated sections.' (Site from DM).	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 16:20:52
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections and update accordingly as it appears some responses are missing. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 02:59:51
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered 'No (N)'	Christina Bacher (b) (4) (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered 'No (N)'	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:56:36
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Un-verified.	Isaac Perez (b) (4)	07 Jan 2021 16:20:42
User entered 'No (N)' reason for change: Data Entry Error	Isaac Perez (b) (4)	07 Jan 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:56:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Un-verified.	Isaac Perez (b) (4)	07 Jan 2021 16:20:42
User entered 'No (N)' reason for change: Data Entry Error	Isaac Perez (b) (4)	07 Jan 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:56:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Un-verified.	Isaac Perez (b) (4)	07 Jan 2021 16:20:42
User entered 'No (N)' reason for change: Data Entry Error	Isaac Perez (b) (4)	07 Jan 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered 'No (N)'	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:57:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Un-verified.	Isaac Perez (b) (4)	07 Jan 2021 16:20:42
User entered 'No (N)' reason for change: Data Entry Error	Isaac Perez (b) (4)	07 Jan 2021 16:20:42
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered 'No (N)'	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:54:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:48:09
User entered empty.	Christina Bacher (b) (4)	04 Dec 2020 15:17:42

US3632107

Folder: Covid-19 Assessment 23 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:54:03

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:11
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:03:03
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) Kelly Likos (b) (4) (b) (4)	09 Feb 2021 16:12:00

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:54:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User accepted default value 'Day 3 (Day 3)'	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:54:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:53:13
User entered 'No (N)'	Christina Bacher (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:54:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:53:14
User entered empty.	Christina Bacher (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:54:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User accepted default value 'Day 5 (Day 5)'	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:54:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:53:07
User entered 'Yes (Y)'	Christina Bacher (b) (4)	30 Nov 2020 18:18:49
	(b) (4)	

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:54:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:53:09
User entered '28 Nov 2020'	Christina Bacher (b) (4)	30 Nov 2020 18:18:49
	(b) (4)	

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:54:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User accepted default value 'Day 7 (Day 7)'	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:54:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:53:02
User entered 'Yes (Y)'	Christina Bacher (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:54:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 21:53:04
User entered '30 Nov 2020'	Christina Bacher (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:54:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User accepted default value 'Day 9 (Day 9)'	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:54:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:52:58
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 18:39:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 18:39:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Christina Bacher (b) (4) (b) (4)	07 Dec 2020 18:39:13
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 18:18:49
User entered empty.	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:54:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:52:59
User entered '2 Dec 2020' reason for change: New Information	Christina Bacher (b) (4)	07 Dec 2020 18:39:13
User entered empty.	(b) (4)	
	Christina Bacher (b) (4)	30 Nov 2020 18:18:49
	(b) (4)	

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:54:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User accepted default value 'Day 14 (Day 14)'	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:54:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 21:52:49
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 18:36:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 18:36:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Christina Bacher (b) (4) (b) (4)	07 Dec 2020 18:36:22
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 18:18:49
User entered empty.	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:54:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 21:52:52
User entered '7 Dec 2020' reason for change: Data Entry Error	Christina Bacher (b) (4)	07 Dec 2020 18:36:22
User entered empty.	(b) (4)	
	Christina Bacher (b) (4)	30 Nov 2020 18:18:49
	(b) (4)	

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:54:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User accepted default value 'Day 21 (Day 21)'	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:54:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:14:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Dec 2020 13:17:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Dec 2020 13:17:35
User entered 'Yes (Y)' reason for change: New Information	Christina Bacher (b) (4)	15 Dec 2020 13:17:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Nov 2020 18:18:49
User entered empty.	System	30 Nov 2020 18:18:49
	Christina Bacher (b) (4)	30 Nov 2020 18:18:49
	(b) (4)	

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:54:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:14:43
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 05:21:13
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Sample shipped on 15DEC2020. Accession # 1F634236570. Tracking # 8159974426720200' (Site from DM).	Christina Bacher (b) (4) (b) (4)	15 Feb 2021 16:29:50
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 06:35:50
User entered '14 Dec 2020' reason for change: New Information	Christina Bacher (b) (4) (b) (4)	15 Dec 2020 13:17:35
User entered empty.	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:54:03

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
User accepted default value 'Day 28 (Day 28)'	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:54:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:14:56
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Query 'Per CDM: Kindly do not close the query until data is updated. Thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:13:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Dec 2020 03:12:55
User entered 'Yes (Y)' reason for change: New Information	Christina Bacher (b) (4)	21 Dec 2020 16:06:47
User opened query 'Per CDM: Kindly do not close the query until data is updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 06:13:03
Query 'Data is required. Please complete.' answered with 'Day 28 visit pending, scheduled for 21DEC. saliva to be collected at that time' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 16:43:44
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 18:18:49
User entered empty.	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:54:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:03:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:15:03
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '21 Dec 2020' reason for change: New Information	(b) (4)	
User entered empty.	Christina Bacher (b) (4)	21 Dec 2020 16:06:47
	(b) (4)	30 Nov 2020 18:18:49

US3632107

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 21:42:33
User entered 'Yes (Y)'	Christina Bacher (b) (4)	24 Nov 2020 16:53:13
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User closed query 'Per GCL Lab Reconciliation: Saliva: Re-query: Thanks for the confirmation, however, please review the preclaus data and update the sample sent date and actual sample collection date to reflect correctly in PPD portal, confirm the same in query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 03:48:47
Query 'Per GCL Lab Reconciliation: Saliva: Re-query: Thanks for the confirmation, however, please review the preclaus data and update the sample sent date and actual sample collection date to reflect correctly in PPD portal, confirm the same in query response.' answered with 'Date on PPD portal has been updated to match eCRF collection date.' (Site from DM).	Isaac Perez (b) (4) (b) (4)	17 Mar 2021 12:23:47
User opened query 'Per GCL Lab Reconciliation: Saliva: Re-query: Thanks for the confirmation, however, please review the preclaus data and update the sample sent date and actual sample collection date to reflect correctly in PPD portal, confirm the same in query response.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:22:32
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 05:21:42
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'Sample was collected on 14Dec2020 and shipped on 15Dec2020. ' (Site from DM).	Christina Bacher (b) (4) (b) (4)	15 Feb 2021 16:30:38

US3632107

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 07:31:38
	(b) (4), (b) (6)	02 Dec 2020 21:42:33
User entered '24 Nov 2020'	Christina Bacher (b) (4)	24 Nov 2020 16:53:13
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 21:42:33
User entered 'Clinic (Clinic)'	Christina Bacher (b) (4)	24 Nov 2020 16:53:13
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	24 Nov 2020 16:53:13

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:03:25
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	24 Nov 2020 16:56:02

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:03:25
User entered '24 Nov 2020'	Christina Bacher (b) (4)	24 Nov 2020 16:56:02
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:03:25
User entered '10:19'	Christina Bacher (b) (4)	24 Nov 2020 16:56:02
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 10:19'	System	24 Nov 2020 16:56:02

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:03:25
User entered '66' in	Christina Bacher (b) (4)	24 Nov 2020 16:56:02
DataPoint set to visible.	(b) (4)	
	System	24 Nov 2020 16:53:13

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:03:25
User entered '186.4' lb	Christina Bacher (b) (4)	24 Nov 2020 16:56:02
DataPoint set to visible.	(b) (4)	
	System	24 Nov 2020 16:53:13

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:03:25
User entered '97.9' F	Christina Bacher (b) (4)	24 Nov 2020 16:56:02
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:03:25
User entered 'Oral (Oral)'	Christina Bacher (b) (4)	24 Nov 2020 16:56:02
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:03:25
User entered empty.	Christina Bacher (b) (4) (b) (4)	24 Nov 2020 16:56:02

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:03:25
User entered '64'	Christina Bacher (b) (4)	24 Nov 2020 16:56:02
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Nov 2020 16:56:02

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:03:25
User entered '14'	Christina Bacher (b) (4)	24 Nov 2020 16:56:02
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Nov 2020 16:56:02

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:03:25
User entered '124'	Christina Bacher (b) (4)	24 Nov 2020 16:56:02
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Nov 2020 16:56:02

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:03:25
User entered '73'	Christina Bacher (b) (4)	24 Nov 2020 16:56:02
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Nov 2020 16:56:02

US3632107

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:04:32
User entered 'Yes (Y)'	Christina Bacher (b) (4)	24 Nov 2020 16:56:08
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:04:32
User entered '24 Nov 2020'	Christina Bacher (b) (4)	24 Nov 2020 16:56:08
	(b) (4)	

US3632107

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 24 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 24 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Per source documentation, blood specimens collected and submitted 24 NOV 2020' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 08:14:40
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 24 NOV 2020 is recorded under Illness Visit(1) Day 1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 14:48:42
User entered 'Yes (Y)'	(b) (4), (b) (6) Christina Bacher (b) (4) (b) (4)	04 Dec 2020 03:13:29 03 Dec 2020 17:04:53 24 Nov 2020 16:56:15

US3632107

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:54:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:04:53
User entered '24 Nov 2020'	Christina Bacher (b) (4) (b) (4)	24 Nov 2020 16:56:15

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:00
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:05:07

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:00
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '21 Dec 2020'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:05:07

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:00
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:54
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Clinic (Clinic)'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:05:07

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:00
User entered 'SICKD28'	System	21 Dec 2020 16:05:07

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '21 Dec 2020'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '10:20'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
User entered '21 Dec 2020 10:20'	System	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '66' in	(b) (4) Christina Bacher (b) (4)	21 Dec 2020 16:06:19
DataPoint set to visible.	(b) (4) System	21 Dec 2020 16:05:07

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '189.6' lb	(b) (4) Christina Bacher (b) (4)	21 Dec 2020 16:06:19
DataPoint set to visible.	(b) (4) System	21 Dec 2020 16:05:07

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '97.4' F	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (Oral)'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '69'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
User entered 'bpm'	System	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '14'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
User entered 'breaths/min'	System	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '137'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
User entered 'mmHg'	System	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:10:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '73'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07
User entered 'mmHg'	System	21 Dec 2020 16:06:19

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:07

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:26

US3632107

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:44:31
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:26

US3632107

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:54:03

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:26
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:11:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	(b) (4) Christina Bacher (b) (4) (b) (4)	21 Dec 2020 16:06:33

US3632107

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:54:03

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:55:26
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:11:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-COV2 sample dated 21 DEC 2020 is still reflecting as "Missing in PPD GCL", please kindly provide Accession number and tracking info, so that PPD GCL will take tracking number and track the shipment status and confirm to us, if the sample is in transit or lost in transit, so that all the old samples which are still "Missing in GCL" can be closed instead of querying to and fro. Thank you.	(b) (4), (b) (6)	08 Feb 2021 13:22:50
' canceled (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-COV2 sample dated 21 DEC 2020 is still reflecting as "Missing in PPD GCL", please kindly provide Accession number and tracking info, so that PPD GCL will take tracking number and track the shipment status and confirm to us, if the sample is in transit or lost in transit, so that all the old samples which are still "Missing in GCL" can be closed instead of querying to and fro. Thank you.	(b) (4), (b) (6)	08 Jan 2021 08:10:45
' (Site from DM).		
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 21 DEC 2020 is recorded under Convalescence Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped, and if applicable please update at PPD portal or raise a DCF request for updating the missing SARS sample dated 21 DEC 2020 in vendor database. Thank you. '	(b) (4), (b) (6)	08 Jan 2021 08:10:12
canceled (Site from DM).		

US3632107

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:54:03

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 21 DEC 2020 is recorded under Convalescence Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped, and if applicable please update at PPD portal or raise a DCF request for updating the missing SARS sample dated 21 DEC 2020 in vendor database. Thank you. ' (Site from DM). User entered '21 Dec 2020'	(b) (4), (b) (6)	07 Jan 2021 18:53:20
	Christina Bacher (b) (4)	21 Dec 2020 16:06:33
	(b) (4)	

US3632107

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

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	14 Jan 2021 16:57:05

US3632107

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

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '14 Jan 2021'	Christina Bacher (b) (4)	14 Jan 2021 16:57:05

US3632107

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

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Clinic (Clinic)'	Christina Bacher (b) (4)	14 Jan 2021 16:57:05

US3632107

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

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 16:57:05

US3632107

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

Form: Unblinding

Generated On: 11 Aug 2021 22:54:03

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '14 Jan 2021'	Christina Bacher (b) (4)	14 Jan 2021 16:57:17

US3632107

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

Form: Unblinding

Generated On: 11 Aug 2021 22:54:03

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:28:45

US3632107

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

Form: Unblinding

Generated On: 11 Aug 2021 22:54:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	14 Jan 2021 16:57:17

US3632107

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

Form: Unblinding

Generated On: 11 Aug 2021 22:54:03

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	12 Apr 2021 01:36:21
User closed query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:47:11
Query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:13:14
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 15:12:52
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Apr 2021 15:12:52
User opened query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 14:54:10
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'AMENDMENT 5 (AMENDMENT 5)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:28:45

US3632107

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

Form: Unblinding

Generated On: 11 Aug 2021 22:54:03

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '14 Jan 2021'	Christina Bacher (b) (4)	14 Jan 2021 16:57:17

US3632107

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

Form: Unblinding

Generated On: 11 Aug 2021 22:54:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Placebo (Placebo)'	Christina Bacher (b) (4)	14 Jan 2021 16:57:17

US3632107

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

Form: Unblinding

Generated On: 11 Aug 2021 22:54:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 09:43:37
User entered 'Placebo (Placebo)'	Christina Bacher (b) (4)	14 Jan 2021 16:57:17
	(b) (4)	

US3632107

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

Form: Unblinding

Generated On: 11 Aug 2021 22:54:03

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 09:43:37
User entered 'Placebo (Placebo)'	Christina Bacher (b) (4)	14 Jan 2021 16:57:17
	(b) (4)	

US3632107

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

Form: Unblinding

Generated On: 11 Aug 2021 22:54:03

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	14 Jan 2021 16:57:17

US3632107

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

Form: Unblinding

Generated On: 11 Aug 2021 22:54:03

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered '1'	System	14 Jan 2021 16:57:17

US3632107

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

Form: Unblinding

Generated On: 11 Aug 2021 22:54:03

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'I'	System	14 Jan 2021 16:57:17

US3632107

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '66' in	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered missing code ND - Not Done.	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered empty.	System	14 Jan 2021 17:02:25
DataPoint set to visible.	System	14 Jan 2021 16:57:17

US3632107

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '66' in	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered missing code ND - Not Done.	(b) (4) Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered empty.	System	14 Jan 2021 17:02:25
DataPoint set to visible.	System	14 Jan 2021 16:57:17

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User accepted default value 'Pre-Dose (PREDOSE)'	Christina Bacher (b) (4) (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '14 Jan 2021'	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '10:10'	(b) (4) Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered '14 Jan 2021 10:10'	System	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '97.9' F	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (Oral)'	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '61'	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'bpm'	System	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '16'	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'breaths/min'	System	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '139'	(b) (4) Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'mmHg'	System	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '76'	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'mmHg'	System	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '66' in	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered missing code ND - Not Done.	(b) (4) Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:54:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered empty.	System	14 Jan 2021 17:02:25
DataPoint set to visible.	System	14 Jan 2021 16:57:17

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User accepted default value 'Post-Dose (POSTDOSE)'	Christina Bacher (b) (4) (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '14 Jan 2021'	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '11:42'	(b) (4) Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered '14 Jan 2021 11:42'	System	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '97.7' F	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (Oral)'	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '51'	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'bpm'	System	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '16'	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'breaths/min'	System	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '129'	Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'mmHg'	System	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '76'	(b) (4) Christina Bacher (b) (4)	14 Jan 2021 17:02:25

US3632107

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'mmHg'	System	14 Jan 2021 17:02:25

US3632107

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	14 Jan 2021 17:02:54

US3632107

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '14 Jan 2021'	Christina Bacher (b) (4)	14 Jan 2021 17:02:54

US3632107

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

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	14 Jan 2021 17:03:31

US3632107

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

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Christina Bacher (b) (4)	14 Jan 2021 17:03:31

US3632107

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

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

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)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	14 Jan 2021 17:03:31

US3632107

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

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'mRNA-1273'	System	14 Jan 2021 17:03:31
DataPoint set to visible.	System	14 Jan 2021 16:57:17

US3632107

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

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '14 Jan 2021'	Christina Bacher (b) (4)	14 Jan 2021 17:03:31

US3632107

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

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '11:11'	Christina Bacher (b) (4)	14 Jan 2021 17:03:31

US3632107

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

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered '14 Jan 2021 11:11'	System	14 Jan 2021 17:03:31

US3632107

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

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Left Arm (LEFT ARM)'	Christina Bacher (b) (4)	14 Jan 2021 17:03:31

US3632107

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

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'ONCE'	System	14 Jan 2021 17:03:31

US3632107

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

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 17:03:31

US3632107

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	14 Jan 2021 16:57:30

US3632107

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '14 Jan 2021'	Christina Bacher (b) (4)	14 Jan 2021 16:57:30

US3632107

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '09:50'	Christina Bacher (b) (4)	14 Jan 2021 16:57:30

US3632107

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered '14 Jan 2021 09:50'	System	14 Jan 2021 16:57:30

US3632107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:54:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	14 Jan 2021 16:57:40

US3632107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '14 Jan 2021'	Christina Bacher (b) (4)	14 Jan 2021 16:57:40

US3632107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:54:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '09:52'	Christina Bacher (b) (4)	14 Jan 2021 16:57:40

US3632107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:54:03

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered '14 Jan 2021 09:52'	System	14 Jan 2021 16:57:40

US3632107

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

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	21 Jan 2021 18:41:44

US3632107

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

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:08:55
User entered 'I'	System	21 Jan 2021 18:41:44

US3632107

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:10
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	21 Jan 2021 18:41:53

US3632107

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:10
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '21 Jan 2021'	Isaac Perez (b) (4)	21 Jan 2021 18:41:53

US3632107

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:10
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Contact Made (CONTACT MADE)'	Isaac Perez (b) (4)	21 Jan 2021 18:41:53

US3632107

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:10
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	21 Jan 2021 18:41:53

US3632107

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:10
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	21 Jan 2021 18:41:57

US3632107

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:10
User entered 'I'	System	21 Jan 2021 18:41:57

US3632107

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:26:10
User entered 'I'	System	21 Jan 2021 18:41:57
DataPoint set to visible.	System	21 Jan 2021 18:41:57

US3632107

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	08 Feb 2021 14:13:21

US3632107

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '8 Feb 2021'	Christina Bacher (b) (4)	08 Feb 2021 14:13:21

US3632107

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Clinic (Clinic)'	Christina Bacher (b) (4)	08 Feb 2021 14:13:21

US3632107

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User entered 'OLD29'	System	08 Feb 2021 14:13:21

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User accepted default value 'Pre-Dose (PREDOSE)'	Christina Bacher (b) (4)	08 Feb 2021 14:15:03
	(b) (4)	

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '8 Feb 2021'	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '08:44'	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User entered '8 Feb 2021 08:44'	System	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '97.0' F	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (Oral)'	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '59'	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User entered 'bpm'	System	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '14'	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User entered 'breaths/min'	System	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '134'	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User entered 'mmHg'	System	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '80'	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User entered 'mmHg'	System	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User accepted default value 'Post-Dose (POSTDOSE)'	Christina Bacher (b) (4) (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 16:07:59
User entered 'Yes (Y)' reason for change: New Information	Catherine Abrams (b) (4)	08 Feb 2021 16:07:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	08 Feb 2021 14:15:03
	Christina Bacher (b) (4)	08 Feb 2021 14:15:03
	(b) (4)	

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '8 Feb 2021' reason for change: New Information	Catherine Abrams (b) (4)	08 Feb 2021 16:07:59
User entered empty.	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '10:57' reason for change: New Information	Catherine Abrams (b) (4)	08 Feb 2021 16:07:59
User entered empty.	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User entered '8 Feb 2021 10:57'	System	08 Feb 2021 16:07:59
User entered empty.	System	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '98.1' F reason for change: New Information	Catherine Abrams (b) (4)	08 Feb 2021 16:07:59
User entered empty.	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (Oral)' reason for change: New Information	Catherine Abrams (b) (4)	08 Feb 2021 16:07:59
User entered empty.	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '56' reason for change: New Information	Catherine Abrams (b) (4)	08 Feb 2021 16:07:59
User entered empty.	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User entered 'bpm'	System	08 Feb 2021 16:07:59
User entered empty.	System	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '14' reason for change: New Information	Catherine Abrams (b) (4)	08 Feb 2021 16:07:59
User entered empty.	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User entered 'breaths/min'	System	08 Feb 2021 16:07:59
User entered empty.	System	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '135' reason for change: New Information	Catherine Abrams (b) (4)	08 Feb 2021 16:07:59
User entered empty.	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User entered 'mmHg'	System	08 Feb 2021 16:07:59
User entered empty.	System	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '86' reason for change: New Information	Catherine Abrams (b) (4)	08 Feb 2021 16:07:59
User entered empty.	Christina Bacher (b) (4)	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:40
User entered 'mmHg'	System	08 Feb 2021 16:07:59
User entered empty.	System	08 Feb 2021 14:15:03

US3632107

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	08 Feb 2021 14:15:14

US3632107

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '8 Feb 2021'	Christina Bacher (b) (4)	08 Feb 2021 14:15:14

US3632107

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	08 Feb 2021 16:05:48

US3632107

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Catherine Abrams (b) (4)	08 Feb 2021 16:05:48

US3632107

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

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)	30 Apr 2021 18:10:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Catherine Abrams (b) (4)	08 Feb 2021 16:05:48

US3632107

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User entered 'mRNA-1273'	System	08 Feb 2021 16:05:48
DataPoint set to visible.	System	21 Jan 2021 18:41:57

US3632107

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '8 Feb 2021'	Catherine Abrams (b) (4)	08 Feb 2021 16:05:48

US3632107

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '10:26'	Catherine Abrams (b) (4)	08 Feb 2021 16:05:48

US3632107

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User entered '8 Feb 2021 10:26'	System	08 Feb 2021 16:05:48

US3632107

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Left Arm (LEFT ARM)'	Catherine Abrams (b) (4)	08 Feb 2021 16:05:48

US3632107

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User entered 'ONCE'	System	08 Feb 2021 16:05:48

US3632107

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:54:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 16:05:48

US3632107

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Catherine Abrams (b) (4)	08 Feb 2021 16:05:55

US3632107

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:10:39
User entered 'I'	System	08 Feb 2021 16:05:55

US3632107

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:01:52
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Feb 2021 18:51:48

US3632107

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:01:52
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '15 Feb 2021'	Aastha KC (b) (4)	22 Feb 2021 18:51:48

US3632107

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:01:52
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Contact Made (CONTACT MADE)'	Aastha KC (b) (4)	22 Feb 2021 18:51:48

US3632107

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:54:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:01:52
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	(b) (4) Aastha KC (b) (4) (b) (4)	22 Feb 2021 18:51:48

US3632107

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:01:52
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Yes (Y)'	Aastha KC (b) (4)	22 Feb 2021 18:51:53

US3632107

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:54:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:01:52
User entered 'I'	System	22 Feb 2021 18:51:53

US3632107

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Yes (Y)'	Christina Bacher (b) (4)	11 Mar 2021 15:46:13

US3632107

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '11 Mar 2021'	Christina Bacher (b) (4)	11 Mar 2021 15:46:13

US3632107

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Clinic (Clinic)'	Christina Bacher (b) (4)	11 Mar 2021 15:46:13

US3632107

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:54:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User entered 'OLD57'	System	11 Mar 2021 15:46:13

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'No (N)'	Christina Bacher (b) (4)	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	Christina Bacher (b) (4)	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	Christina Bacher (b) (4)	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User entered empty.	System	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	Christina Bacher (b) (4)	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	Christina Bacher (b) (4)	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	Christina Bacher (b) (4)	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	Christina Bacher (b) (4)	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User entered empty.	System	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	Christina Bacher (b) (4)	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User entered empty.	System	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	Christina Bacher (b) (4)	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User entered empty.	System	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	(b) (4) Christina Bacher (b) (4)	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User entered empty.	System	11 Mar 2021 15:47:22

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08

US3632107

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:54:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08

US3632107

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'No (N)'	(b) (4) Christina Bacher (b) (4)	11 Mar 2021 15:48:20

US3632107

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:54:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered empty.	Christina Bacher (b) (4)	11 Mar 2021 15:48:20

US3632107

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'Yes (Y)'	Christina Bacher (b) (4)	11 Mar 2021 15:48:50

US3632107

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '11 Mar 2021'	Christina Bacher (b) (4)	11 Mar 2021 15:48:50

US3632107

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '10:33'	Christina Bacher (b) (4)	11 Mar 2021 15:48:50

US3632107

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:54:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:22:08
User entered '11 Mar 2021 10:33'	System	11 Mar 2021 15:48:50

US3632107

Folder: Unscheduled 23 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:54:03

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '23 Nov 2020'	Sarah Wiatrek (b) (4)	03 Dec 2020 20:24:01

US3632107

Folder: Unscheduled 23 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:54:03

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User closed query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from DM).	(b) (4)	
Query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' answered with 'This was a safety call there is no procedure' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:03:22
Query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' answered with 'This was a safety call there is no procedure' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 20:32:51
User opened query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 16:41:39
Query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' canceled (Site from System).	(b) (4), (b) (6)	09 Mar 2021 16:41:33
User opened query 'Procedure(s) performed is missing. Please check at least one procedure from the options provided.' (Site from System).	System	03 Dec 2020 20:24:01
User entered '0'	Sarah Wiatrek (b) (4)	03 Dec 2020 20:24:01
	(b) (4)	

US3632107

Folder: Unscheduled 23 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:54:03

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '0'	Sarah Wiatrek (b) (4)	03 Dec 2020 20:24:01

US3632107

Folder: Unscheduled 23 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:54:03

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '0'	Sarah Wiatrek (b) (4)	03 Dec 2020 20:24:01

US3632107

Folder: Unscheduled 23 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:54:03

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:17
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '0'	Sarah Wiatrek (b) (4)	03 Dec 2020 20:24:01

US3632107

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:54:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:31:32
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 4 - 27Sep2020; end date: Day 8 - 01Oct2020). 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) (4), (b) (6)	16 Feb 2021 18:20:37
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 4 - 27Sep2020; end date: Day 8 - 01Oct2020). 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 Joint Aches as an AE per protocol' (Site from DM).	Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:52
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 4 - 27Sep2020; end date: Day 8 - 01Oct2020). 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)	05 Feb 2021 16:39:38
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 19:05:04
User entered 'Yes (Y)'	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 19:05:43

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:03
User entered 'USA-US120-2020-mRNA-1273-P301000007'	System	03 Dec 2020 02:40:58
User entered 'New'	(b) (4), (b) (6)	03 Dec 2020 02:40:58

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
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)	30 Nov 2020 19:41:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Nov 2020 19:41:16
Data point term sent to Coder	System	30 Nov 2020 19:40:13
User entered 'symptomatic COVID-19'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Please revisit response as CCGs indicate cases of confirmed SARS CoV-2 should be considered MAAEs.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:48:51
Query 'Please revisit response as CCGs indicate cases of confirmed SARS CoV-2 should be considered MAAEs.' answered with 'Participant tested positive outside of the study and then came in for illness visit. Updated to Yes for MAE.' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 14:28:43
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Dec 2020 14:28:02
User opened query 'Please revisit response as CCGs indicate cases of confirmed SARS CoV-2 should be considered MAAEs.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 02:01:33
User entered 'No (N)'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '17 Nov 2020'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)' reason for change: Data Entry Error	Isaac Perez (b) (4)	15 Feb 2021 19:36:46
User entered 'Yes (Y)'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:58
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 21:22:21
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 17:19:12
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Updated end date' (Site from Safety).	Isaac Perez (b) (4)	15 Feb 2021 19:37:18
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	15 Feb 2021 19:36:53
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	15 Feb 2021 19:36:53
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	15 Feb 2021 19:36:46
User entered '21 Dec 2020' reason for change: Data Entry Error	Isaac Perez (b) (4)	15 Feb 2021 19:36:46
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 12:33:43
User entered empty.	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Grade 1/Mild (Grade 1/Mild)'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Not Related (NOT RELATED)'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Not Related (NOT RELATED)'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Please consider if action taken with IP would be more properly captured as not applicable as subject had already completed visit 2 prior to AE start date.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:49:17
Query 'Please consider if action taken with IP would be more properly captured as not applicable as subject had already completed visit 2 prior to AE start date.' answered with 'Updated to Not applicable as this occurred after dose 2. ' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 14:28:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Dec 2020 14:28:02
User opened query 'Please consider if action taken with IP would be more properly captured as not applicable as subject had already completed visit 2 prior to AE start date.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 02:03:04
User entered 'None (NONE)'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please confirm and consider to complete the ConMed forms. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 04:23:42
Query 'Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please confirm and consider to complete the ConMed forms. Thank you. ' answered with 'Updated ConMed forms.' (Site from DM).	Isaac Perez (b) (4) (b) (4)	07 Jan 2021 15:51:07
User opened query 'Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please confirm and consider to complete the ConMed forms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 16:29:32
User entered 'I'	Christina Bacher (b) (4) (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 21:22:32
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'UPdated selection' (Site from Safety).	(b) (4)	
	Isaac Perez (b) (4)	15 Feb 2021 19:39:00
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Isaac Perez (b) (4)	15 Feb 2021 19:36:53
Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 12:33:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Christina Bacher (b) (4)	30 Nov 2020 19:39:23
	(b) (4)	

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Participant developed symptoms on 11/17/20. He tested positive outside of the study and then presented for illness visit on 11/24/20.'	(b) (4) Christina Bacher (b) (4)	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:54:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 14:28:02
User entered '0'	System	30 Nov 2020 19:39:23

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal haemorrhages NEC, HLT: Intestinal haemorrhages, PT: Rectal haemorrhage, LLT: Rectal bleeding - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 20:15:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 20:15:51
Data point term sent to Coder	System	02 Dec 2020 20:15:04
User entered 'Rectal bleeding'	Christina Bacher (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
User signature succeeded.	Colleen Kelley (b) (4)	28 Apr 2021 22:19:05
User closed query 'Per MM: please clarify why for this has been ticked that this is a confirmed COVID infection.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 16:47:44
Query 'Per MM: please clarify why for this has been ticked that this is a confirmed COVID infection.' answered with 'corrected to 'no'. This was a result to NSAID use due to concurrent covid infection but covid infection already listed as separate AE, thus this was changed to no' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 13:21:26
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 13:20:12
Signature has been broken.	(b) (4), (b) (6)	26 Apr 2021 13:20:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 13:20:12
User opened query 'Per MM: please clarify why for this has been ticked that this is a confirmed COVID infection.' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 15:37:24
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:36:00
User closed query 'This is checked Yes n the source; please review, verify and reconcile EDC with the source.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 22:35:57
Query 'This is checked Yes n the source; please review, verify and reconcile EDC with the source.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 14:10:28
Signature has been broken.	(b) (4), (b) (6)	13 Apr 2021 14:10:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 14:10:00
User opened query 'This is checked Yes n the source; please review, verify and reconcile EDC with the source.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:22:18

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:58
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 17:58:55
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'corrected' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 17:18:50
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 17:18:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 17:18:42
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 16:48:36
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:36:08
User closed query 'Start date is noted as 23Nov20 in the chart; please verify and update.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 22:36:07
Query 'Start date is noted as 23Nov20 in the chart; please verify and update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:54:07
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 17:50:32
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 17:50:32
User opened query 'Start date is noted as 23Nov20 in the chart; please verify and update.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:25:22
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:24:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '24 Nov 2020'	Christina Bacher (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
User entered empty.	System	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:36:16
User closed query 'Please confirm this is still ongoing; chart notes end date as 07Dec20.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 22:36:14
Query 'Please confirm this is still ongoing; chart notes end date as 07Dec20.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:54:41
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 17:50:32
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Apr 2021 17:50:32
User opened query 'Please confirm this is still ongoing; chart notes end date as 07Dec20.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:26:03
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:25:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Christina Bacher (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:36:19
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 17:50:32
User entered '07 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	12 Apr 2021 17:50:32
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:26:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Christina Bacher (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
User entered empty.	System	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Not Related (NOT RELATED)'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Not Related (NOT RELATED)'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Per CDM: Per CCG pg.38, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4)	
Query 'Per CDM: Per CCG pg.38, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' answered with 'Updated selection.' (Site from DM).	Isaac Perez (b) (4)	10 Dec 2020 13:56:56
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 13:56:47
User opened query 'Per CDM: Per CCG pg.38, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 11:25:17
User entered 'None (NONE)'	Christina Bacher (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	02 Dec 2020 20:15:02
User entered '1' reason for change: Data Entry Error	Christina Bacher (b) (4)	02 Dec 2020 20:15:02
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	02 Dec 2020 20:14:53
User entered '0'	Christina Bacher (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:36:28
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 17:50:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	12 Apr 2021 17:50:32
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:26:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Christina Bacher (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Participant was taking NSAIDs when his symptoms of COVID started and noticed the immediate onset of rectal bleeding. He has since stopped all medications and the rectal bleeding has persisted.'	(b) (4) Christina Bacher (b) (4) (b) (4)	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
User entered '0'	System	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14
User entered '0'	System	02 Dec 2020 20:14:53

US3632107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:54:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:57:14

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:45:19
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:28:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:58
User closed query 'Per CDM Re-Query: Please clarify the update made as the specific location of Joint aches is still missing. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 10:38:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 19:56:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 19:56:37
Data point term sent to Coder	System	15 Mar 2021 19:40:46
Query 'Per CDM Re-Query: Please clarify the update made as the specific location of Joint aches is still missing. Thank you' answered with 'uUPDATED' (Site from DM).	Isaac Perez (b) (4) (b) (4)	15 Mar 2021 19:40:17
Coding entries removed.	Isaac Perez (b) (4) (b) (4)	15 Mar 2021 19:40:10
Signature has been broken.	Isaac Perez (b) (4) (b) (4)	15 Mar 2021 19:40:10
User entered 'GENERAL JOINT ACHES' reason for change: Data Entry Error	Isaac Perez (b) (4) (b) (4)	15 Mar 2021 19:40:10
User opened query 'Per CDM Re-Query: Please clarify the update made as the specific location of Joint aches is still missing. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 16:30:16
User closed query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 16:30:16

PRODUCTION RELEASE (v12.003
EAB) (1725)

2706 of 3056

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 15:36:42
User opened query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:40:33
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Feb 2021 19:50:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 19:50:41
Data point term sent to Coder	System	15 Feb 2021 19:49:33
User entered 'Joint Aches'	Isaac Perez (b) (4)	15 Feb 2021 19:49:24
	(b) (4)	

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
User signature succeeded.	Colleen Kelley (b) (4)	22 Apr 2021 15:42:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:45:34
User closed query 'This response is noted as no in the chart; please verify and update response.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 22:36:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 14:11:58
Query 'This response is noted as no in the chart; please verify and update response.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 17:56:06
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 17:55:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 17:55:38
User opened query 'This response is noted as no in the chart; please verify and update response.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:37
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:29:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Mar 2021 18:21:58
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 16:30:48
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 15:37:44

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 15:36:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 15:36:33
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:40:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
	(b) (4)	
User entered 'No (N)'	Isaac Perez (b) (4)	15 Feb 2021 19:49:24
	(b) (4)	

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '27 Sep 2020'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
User entered empty.	System	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '1 Oct 2020'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
User entered empty.	System	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Related (RELATED)'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Not Related (NOT RELATED)'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'None (NONE)'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User closed query 'Per CDM, DM CLR RQ: Please note that the indication of CM#8 and #9 is only for MUSCLE ACHES. Please review if JOINT ACHES should be included in the indication of these medications. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:16:37
Query 'Per CDM, DM CLR RQ: Please note that the indication of CM#8 and #9 is only for MUSCLE ACHES. Please review if JOINT ACHES should be included in the indication of these medications. Thank you. ' answered with 'Con Meds 8 and 9 were taken for muscle aches related to muscle soreness, not joint aches' (Site from DM).	Isaac Perez (b) (4) (b) (4)	01 Apr 2021 19:47:07
User opened query 'Per CDM, DM CLR RQ: Please note that the indication of CM#8 and #9 is only for MUSCLE ACHES. Please review if JOINT ACHES should be included in the indication of these medications. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 07:55:26
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded for MUSCLE ACHES that matches this AE during this timeframe. Please review if this is also used for JOINT ACHES and update this field and reconcile terms in CM page.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 07:55:26
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded for MUSCLE ACHES that matches this AE during this timeframe. Please review if this is also used for JOINT ACHES and update this field and reconcile terms in CM page.' answered with 'Please see Conmed #s 8 and 9' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:23:50
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication recorded for MUSCLE ACHES that matches this AE during this timeframe. Please review if this is also used for JOINT ACHES and update this field and reconcile terms in CM page.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:58:00

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

None

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	15 Feb 2021 19:49:30
User entered '1' reason for change: Data Entry Error	Isaac Perez (b) (4)	15 Feb 2021 19:49:30
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	15 Feb 2021 19:49:24
User entered '0'	Isaac Perez (b) (4)	15 Feb 2021 19:49:24
	(b) (4)	

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[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 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:19:44
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) Isaac Perez (b) (4) (b) (4)	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
User entered '0'	System	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05
User entered '0'	System	15 Feb 2021 19:49:24

US3632107

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:54:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:48:05

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:54:03

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:31:32
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 17:21:37

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL, PRODUCTSYNONYM: OMEGA 3 [FISH OIL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 12:23:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 12:23:46
Data point term sent to Coder	System	25 Sep 2020 17:33:49
User entered 'Fish Oil (Omega-3)'	(b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Dietary Supplement'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '1 UNK 2018'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 17:32:49

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:36:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:36:54
Data point term sent to Coder	System	25 Sep 2020 17:35:54
User entered 'Vitamin C'	(b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Dietary Supplement'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '1 UNK 2018'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Isaac Perez (b) (4)	25 Sep 2020 19:07:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).	(b) (4)	25 Sep 2020 19:07:27
User opened query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		25 Sep 2020 17:35:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 17:35:20

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:37:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:37:57
Data point term sent to Coder	System	25 Sep 2020 17:36:56
User entered 'Vitamin D'	(b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Dietary Supplement'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4) System	25 Sep 2020 17:37:35
User entered 'unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 17:37:35
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	25 Sep 2020 17:36:16
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '1 UNK 2018'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 19:07:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:07:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Isaac Perez (b) (4)	25 Sep 2020 19:07:34
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 17:36:16
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 17:36:16

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:38:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:38:45
Data point term sent to Coder	System	25 Sep 2020 17:37:59
User entered 'Vitamin B12'	(b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Dietary Supplement'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '1 UNK 2018'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 19:07:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:07:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Isaac Perez (b) (4)	25 Sep 2020 19:07:42
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 17:37:18
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 17:37:18

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:39:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:39:55
Data point term sent to Coder	System	25 Sep 2020 17:39:02
User entered 'Glucosamine'	(b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Dietary Supplement'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '1 UNK 2018'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:07:57
User entered 'Yes (Y)' reason for change: Data Entry Error	System	25 Sep 2020 19:07:57
User opened query 'Data is required. Please complete.' (Site from System).	Isaac Perez (b) (4)	25 Sep 2020 19:07:57
User entered empty.	(b) (4)	
	System	25 Sep 2020 17:38:27
	(b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 17:38:27

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 19:08:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 19:08:59
Data point term sent to Coder	System	25 Sep 2020 19:08:35
Data point term sent to Coder	System	25 Sep 2020 17:40:05
User entered 'Melatonin'	(b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:08:15
User entered 'No (N)' reason for change: Data Entry Error	System	25 Sep 2020 19:08:15
User opened query 'Data is required. Please complete.' (Site from System).	Isaac Perez (b) (4)	25 Sep 2020 19:08:15
User entered empty.	(b) (4)	25 Sep 2020 17:39:08
	(b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Dietary Supplement'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:08:15
User entered 'once daily (QD)' reason for change: Data Entry Error	System	25 Sep 2020 19:08:15
User opened query 'Data is required. Please complete.' (Site from System).	Isaac Perez (b) (4)	25 Sep 2020 19:08:15
User entered empty.	(b) (4)	
	System	25 Sep 2020 17:39:08
	(b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:08:15
User entered 'Oral (ORAL)' reason for change: Data Isaac Perez Entry Error	System	25 Sep 2020 19:08:15
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Sep 2020 19:08:15
User entered empty.	System	25 Sep 2020 17:39:08
	(b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '1 UNK 2018'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:08:15
User entered 'Yes (Y)' reason for change: Data Entry Error	System	25 Sep 2020 19:08:15
User opened query 'Data is required. Please complete.' (Site from System).	Isaac Perez (b) (4)	25 Sep 2020 19:08:15
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 19:08:15
User entered empty.	System	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 19:08:15
User entered empty.	System	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 19:08:15
User entered empty.	System	25 Sep 2020 17:39:08

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Sep 2020 19:08:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 19:08:58
Data point term sent to Coder	System	25 Sep 2020 19:08:38
Data point term sent to Coder	System	25 Sep 2020 17:40:05
User entered 'Iron'	(b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Dietary Supplement'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:08:30
User entered 'once daily (QD)' reason for change: Data Entry Error	System	25 Sep 2020 19:08:30
User opened query 'Data is required. Please complete.' (Site from System).	Isaac Perez (b) (4)	25 Sep 2020 19:08:30
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:08:30
User entered 'Oral (ORAL)' reason for change: Data Isaac Perez	System	25 Sep 2020 19:08:30
Entry Error	(b) (4)	25 Sep 2020 19:08:30
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 17:39:43
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '1 UNK 2018'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 19:08:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:08:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Isaac Perez (b) (4)	25 Sep 2020 19:08:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 17:39:43
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 19:08:30
User entered empty.	System	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 19:08:30
User entered empty.	System	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 19:08:30
User entered empty.	System	25 Sep 2020 17:39:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 14:02:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 14:02:02
Data point term sent to Coder User entered 'Ibuprofen'	System Isaac Perez (b) (4)	30 Sep 2020 14:00:44 30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:02:48
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' answered with 'muscle aches did not meet AE criteria and is an AR after dose 1. ' (Site from DM).	Christina Bacher (b) (4) (b) (4)	01 Dec 2020 20:49:13

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '200'	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'mg (mg)'	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'twice daily (BID)'	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (ORAL)'	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '28 Sep 2020'	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '28 Sep 2020'	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User entered '2'	System	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User entered '1'	System	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:45
User entered '804 (804)'	System	30 Sep 2020 14:00:43

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
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)	30 Sep 2020 14:03:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 14:03:59
Data point term sent to Coder	System	30 Sep 2020 14:02:53
User entered 'Acetaminophen'	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:50:47
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 15:50:16
User entered 'Muscle Aches'	Isaac Perez (b) (4) (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:02:58
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 19:19:54
User entered '500' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Dec 2020 19:19:47
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 15:50:36
User entered '200'	Isaac Perez (b) (4) (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'mg (mg)'	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'twice daily (BID)'	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (ORAL)'	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '28 Sep 2020' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Feb 2021 18:58:47
Signature has been broken.	Aastha KC (b) (4)	22 Feb 2021 18:57:21
User entered '19 Nov 2020' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Feb 2021 18:57:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '28 Sep 2020'	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '28 Sep 2020' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Feb 2021 18:58:47
Signature has been broken.	Aastha KC (b) (4)	22 Feb 2021 18:57:21
User entered '22 Nov 2020' reason for change: Data Entry Error	Aastha KC (b) (4)	22 Feb 2021 18:57:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '28 Sep 2020'	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Yes (Y)'	Isaac Perez (b) (4)	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User entered '2'	System	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User entered '1'	System	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:47
User entered '804 (804)'	System	30 Sep 2020 14:02:00

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 14:23:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 14:23:40
Data point term sent to Coder	System	07 Jan 2021 15:54:34
User entered 'Aspirin'	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'COVID 19 SYMPTOMS'	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '81'	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'mg (mg)'	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'twice daily (BID)'	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (ORAL)'	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '19 Nov 2020'	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '22 Nov 2020'	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User entered '2'	System	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User entered '1'	System	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:49
User entered '804 (804)'	System	07 Jan 2021 15:53:50

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 14:54:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 14:54:41
Data point term sent to Coder	System	07 Jan 2021 15:55:34
User entered 'DayQuil (Acetaminophen 325 mg/Phenylephrine 5mg/Dextromethorphan HBr 10mg)'	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'COVID 19 SYMPTOMS'	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '325/5/10'	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'mg (mg)'	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'twice daily (BID)'	(b) (4) Isaac Perez (b) (4) (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (ORAL)'	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '19 Nov 2020'	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '22 Nov 2020'	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User entered '2'	System	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User entered '1'	System	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:52
User entered '804 (804)'	System	07 Jan 2021 15:55:31

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: VICKS NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 15:56:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 15:56:40
Data point term sent to Coder	System	07 Jan 2021 16:12:49
User entered 'NyQuil (Acetaminophen 325 mg/Dexfromethorphan HBr 10mg/Doxylamine Succinate 6.25mg)'	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'COVID 19 SYMPTOMS'	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '325/10/6.25'	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'mg (mg)'	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'once daily (QD)'	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (ORAL)'	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '19 Nov 2020'	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '22 Nov 2020'	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User entered '1'	System	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User entered '1'	System	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:57
User entered '804 (804)'	System	07 Jan 2021 16:12:39

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
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)	07 Jan 2021 16:14:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Jan 2021 16:14:41
Data point term sent to Coder	System	07 Jan 2021 16:13:50
User entered 'Acetaminophen'	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'COVID 19 SYMPTOMS'	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '500'	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'mg (mg)'	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'twice daily (BID)'	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (ORAL)'	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '19 Nov 2020'	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '22 Nov 2020'	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User entered '2'	System	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User entered '1'	System	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:31:59
User entered '804 (804)'	System	07 Jan 2021 16:13:23

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: MENTHOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 15:15:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 15:15:40
Data point term sent to Coder	System	07 Jan 2021 16:14:51
User entered 'Halls Cough Drops (Menthol 7.5 mg)'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'COVID 19 SYMPTOMS'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '7.5'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'mg (mg)'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'other (OTHER)'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '6 time per day'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'Oral (ORAL)'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered empty.	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '19 Nov 2020'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '0'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '22 Nov 2020'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	Isaac Perez (b) (4)	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User entered empty.	System	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User entered empty.	System	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:54:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:32:02
User entered empty.	System	07 Jan 2021 16:14:24

US3632107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:54:03

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'No (N)'	(b) (4) Kelly Likos (b) (4) (b) (4)	09 Feb 2021 16:11:40

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'USA-US120-2020-MRNA-1273-P301000007'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'Colleen'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'Kelley'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'GA'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 22:55:01
User entered 'US'	System	03 Dec 2020 02:41:19

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Mar 2021 21:23:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
	(b) (4)	
User entered '2'	System	03 Feb 2021 22:55:13
User entered '1'	System	03 Dec 2020 02:41:19

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'USA-US120-2020-MRNA-1273-P301000007'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'Colleen'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'Kelley'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'GA'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 22:55:01
User entered 'US'	System	03 Dec 2020 02:41:19

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Mar 2021 21:23:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
	(b) (4)	
User entered '2'	System	03 Feb 2021 22:55:13
User entered '1'	System	03 Dec 2020 02:41:19

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:54:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '03/Dec/2020 02:41'	(b) (4) System	03 Dec 2020 02:41:19

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:54:03

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)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 22:55:01
User entered 'I'	(b) (4), (b) (6)	03 Dec 2020 02:41:19

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'USA-US120-2020-MRNA-1273-P301000007'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'Colleen'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'Kelley'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'GA'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 22:55:01
User entered 'US'	System	03 Dec 2020 02:41:19

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Mar 2021 21:23:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
	(b) (4)	
User entered '2'	System	03 Feb 2021 22:55:13
User entered '1'	System	03 Dec 2020 02:41:19

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:54:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered '03/Feb/2021 17:55'	(b) (4) System	03 Feb 2021 22:55:13

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:54:03

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)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 21:23:13
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 22:55:13

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'USA-US120-2020-MRNA-1273-P301000007'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'No (N)'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'Colleen'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'Kelley'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Dec 2020 02:41:14
User entered 'GA'	System	03 Dec 2020 02:40:58

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 22:55:01
User entered 'US'	System	03 Dec 2020 02:41:19

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 11 Aug 2021 22:54:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Mar 2021 21:23:52
User signature succeeded.	Colleen Kelley (b) (4)	22 Feb 2021 17:43:57
	(b) (4)	
User entered '2'	System	03 Feb 2021 22:55:13
User entered '1'	System	03 Dec 2020 02:41:19

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:54:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered '11/Mar/2021 16:23'	(b) (4) System	11 Mar 2021 21:23:52

US3632107

Folder: SAE USA-US120-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:54:03

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)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:21
User signature succeeded.	Colleen Kelley (b) (4)	05 Apr 2021 01:16:31
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 21:23:52