

US3272195 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:23:03

All time stamps listed in this document are displayed in GMT

US3272195

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Participant ID

US3272195

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

US3272195

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:02:40

Generated On: 09 Jun 2021 16:23:03

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

Visit date (dd MMM yyyy)	19 AUG 2020
--------------------------	-------------

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

Folder OID	SCRN
------------	------

US3272195

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Apr 2021 15:02:39

Generated On: 09 Jun 2021 16:23:03

Date of Birth (MMM yyyy)	(b) (6)	1976
Age		44
Age Units		YEARS
Age (Derived)		44
Sex	Female	<input checked="" type="radio"/>
	Male	<input 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		True
Black		False
Asian		False
American Indian or Alaska Native		False
Native Hawaiian or other Pacific Islander		False
Other		False
If race is Other, specify _____		
Unknown		False
Not reported		False

US3272195

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Apr 2021 15:02:39

Generated On: 09 Jun 2021 16:23:03

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3272195

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Apr 2021 15:02:39

Generated On: 09 Jun 2021 16:23:03

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3272195

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Apr 2021 15:02:40

Generated On: 09 Jun 2021 16:23:03

Were any significant conditions reported?

Yes ☒
No ☐

US3272195

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Apr 2021 15:02:39

Generated On: 09 Jun 2021 16:23:03

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3272195

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 15:02:39

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Apr 2021 15:02:39

Generated On: 09 Jun 2021 16:23:03

Condition	GESTATIONAL DIABETES
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3272195

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Apr 2021 15:02:39

Generated On: 09 Jun 2021 16:23:03

Condition	GESTATIONAL DIABETES
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3272195

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Apr 2021 15:02:39

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Apr 2021 15:02:39

Generated On: 09 Jun 2021 16:23:03

Condition	ACID INDIGESTION
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

US3272195

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 15:02:40

Generated On: 09 Jun 2021 16:23:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:51 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 17:51
Height (<i>xxx.x</i>)	152.5 cm
Weight (<i>xxx.x</i>)	78 kg
BMI (<i>xxx.x</i>)	33.53937 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)	

US3272195

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:02:40

Generated On: 09 Jun 2021 16:23:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

US3272195

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 09 Apr 2021 15:02:39

Generated On: 09 Jun 2021 16:23:03

Date of assessment (dd MMM yyyy) 19 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

US3272195

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 09 Apr 2021 15:02:40

Generated On: 09 Jun 2021 16:23:03

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 19 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3272195

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Apr 2021 15:02:40

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Apr 2021 15:02:40

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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

Visit date (dd MMM yyyy)	19 AUG 2020
--------------------------	-------------

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

Folder OID	VISIT1
------------	--------

US3272195

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 105994

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 ☒

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Height	ND - Not Done
Weight	ND - Not Done

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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)	19 AUG 2020
Time of assessment (00:00-23:59)	17:51 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 17:51
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 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)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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)	19 AUG 2020
Time of assessment (00:00-23:59)	19:32 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 19:32
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3272195

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

US3272195

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3272195

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 19:01 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 19:01

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

US3272195

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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

Collection date (dd MMM yyyy)	19 AUG 2020
-------------------------------	-------------

Collection time (00:00-23:59)	18:19 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	19 AUG 2020 18:19
------------------------------------	-------------------

US3272195

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:13	19 AUG 2020 18:13
Nasopharyngeal Swab 2	No		

US3272195

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 19:38

PC Open Date & Time

19 AUG 2020 19:21

PC Close Date & Time

19 AUG 2020 21:51

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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 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):

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

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

PC Time Stamp 20 AUG 2020 08:42

PC Open Date & Time 19 AUG 2020 22:46

PC Close Date & Time 20 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 19:05

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

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

21 AUG 2020 20:21

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 19:14

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 19:24

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 19:41

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

98.0 °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 AUG 2020 17:31

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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

19 AUG 2020 19:41

PC Open Date & Time

19 AUG 2020 19:21

PC Close Date & Time

19 AUG 2020 21:51

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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 AUG 2020 08:42

PC Open Date & Time

19 AUG 2020 22:46

PC Close Date & Time

20 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

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

20 AUG 2020 19:05

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

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

21 AUG 2020 20:21

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

22 AUG 2020 19:14

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

23 AUG 2020 19:24

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

24 AUG 2020 19:41

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

25 AUG 2020 17:31

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 19:41
PC Open Date & Time	19 AUG 2020 19:21
PC Close Date & Time	19 AUG 2020 21:51

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 08:43
PC Open Date & Time	19 AUG 2020 22:46
PC Close Date & Time	20 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 3760

EAB) (1725)

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 19:06
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 3760

EAB) (1725)

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 20:21
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

54 of 3760

EAB) (1725)

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:15
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

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)

56 of 3760

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 19:25
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

58 of 3760

EAB) (1725)

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:42
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

60 of 3760

EAB) (1725)

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 17:31
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3272195

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3272195

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:22:53

Generated On: 09 Jun 2021 16:23:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3272195

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:22:53

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:23:12

Generated On: 09 Jun 2021 16:23:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3272195

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:12

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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)	17 SEP 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 16:05
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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)	17 SEP 2020
Time of assessment (00:00-23:59)	17:30 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 17:30
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3272195

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3272195

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 17 SEP 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3272195

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 16:54 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 16:54

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

US3272195

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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

Collection date (dd MMM yyyy)	17 SEP 2020
-------------------------------	-------------

Collection time (00:00-23:59)	16:13 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	17 SEP 2020 16:13
------------------------------------	-------------------

US3272195

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:10	17 SEP 2020 16:10
Nasopharyngeal Swab 2	No		

US3272195

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 17:25

PC Open Date & Time

17 SEP 2020 17:14

PC Close Date & Time

17 SEP 2020 19:44

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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 98.3 °F

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

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

PC Time Stamp	17 SEP 2020 20:40
PC Open Date & Time	17 SEP 2020 20:39
PC Close Date & Time	18 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 20:10

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

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 ☒

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 SEP 2020 00:19

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 22:16

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 20:15

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 19:32

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 06:33

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 17:25

PC Open Date & Time

17 SEP 2020 17:14

PC Close Date & Time

17 SEP 2020 19:44

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

17 SEP 2020 20:40

PC Open Date & Time

17 SEP 2020 20:39

PC Close Date & Time

18 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

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

18 SEP 2020 20:11

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

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

20 SEP 2020 00:19

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

20 SEP 2020 22:16

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

21 SEP 2020 20:16

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

22 SEP 2020 19:32

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

24 SEP 2020 06:34

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 17:26
PC Open Date & Time	17 SEP 2020 17:14
PC Close Date & Time	17 SEP 2020 19:44

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 20:41
PC Open Date & Time	17 SEP 2020 20:39
PC Close Date & Time	18 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

97 of 3760

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 3760

EAB) (1725)

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

EAB) (1725)

101 of 3760

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 22:17
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

103 of 3760

EAB) (1725)

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 20:16
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

105 of 3760

EAB) (1725)

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 19:33
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

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 ☒

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 06:34
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3272195

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272195

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3272195

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3272195

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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

Visit date (dd MMM yyyy)	15 OCT 2020
--------------------------	-------------

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

Folder OID	VISIT3
------------	--------

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	15:14 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 15:14
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272195

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3272195

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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

Collection date (dd MMM yyyy)	15 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	15:26 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	15 OCT 2020 15:26
------------------------------------	-------------------

US3272195

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	19 OCT 2020 21:26:53
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	02 NOV 2020 06:57:54
Patient Cloud Open Date & Time	02 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	123 of 3760

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	True
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	16 NOV 2020 06:43:33
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 <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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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	05 DEC 2020 19:00:48
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 05:10:39

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☒

Yes ☐

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

20 DEC 2020 08:44:09

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

25 DEC 2020 00:38:25

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

01 JAN 2021 00:01:32

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 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	11 JAN 2021 09:34:13
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 <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 JAN 2021 14:22:07
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 06:04:00

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 <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	30 JAN 2021 22:35:26
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

05 FEB 2021 04:52:30

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 06:18:16
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 <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	19 FEB 2021 06:02:36
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 <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	01 MAR 2021 14:56:05
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

05 MAR 2021 06:35:28

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

12 MAR 2021 06:02:55

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

19 MAR 2021 05:05:32

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 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	30 MAR 2021 14:36:38
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 APR 2021 05:07:42
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 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 APR 2021 06:33:32
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

19 APR 2021 22:13:32

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 08:45:06

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

30 APR 2021 06:11:13

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 <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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 <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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	14 MAY 2021 00:01
Patient Cloud Close Date & Time	18 MAY 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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="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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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="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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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="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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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="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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐ Yes ☐

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

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐
Yes ☐

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

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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="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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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="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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 <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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 <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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐
Yes ☐

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

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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="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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	14 JAN 2022 00:01
Patient Cloud Close Date & Time	18 JAN 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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	28 JAN 2022 00:01
Patient Cloud Close Date & Time	01 FEB 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐
Yes ☐

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

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 <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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	11 MAR 2022 00:01
Patient Cloud Close Date & Time	15 MAR 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 <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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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	25 MAR 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	29 MAR 2022 23:59
---	-------------------

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	08 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 656

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

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

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

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

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

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

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	17 JUN 2022 00:01
Patient Cloud Close Date & Time	21 JUN 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

DAY 705

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

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

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

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

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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	29 JUL 2022 00:01
Patient Cloud Close Date & Time	02 AUG 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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	12 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	16 AUG 2022 23:59
---	-------------------

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐ Yes ☐

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

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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	26 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	30 AUG 2022 23:59
---	-------------------

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐
Yes ☐

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

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐
Yes ☐

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

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

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

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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="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"/>

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3272195

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:23:03

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		01 MAR 2021 14:55:55

US3272195

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3272195

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:22:53

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:22:53

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:22:53

Generated On: 09 Jun 2021 16:23:03

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3272195

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:22:53

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:23:12

Generated On: 09 Jun 2021 16:23:03

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3272195

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:12

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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

Visit date (dd MMM yyyy)	30 MAR 2021
--------------------------	-------------

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

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

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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) _____

US3272195

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

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

US3272195

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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

Collection date (dd MMM yyyy)	30 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	14:43 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	30 MAR 2021 14:43
------------------------------------	-------------------

US3272195

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:23:12

Generated On: 09 Jun 2021 16:23:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272195

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:12

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Date of Contact	02 NOV 2020
Time of Contact	13:24
Date and Time of Contact (derived)	02 NOV 2020 13:24
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	30 OCT 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

326 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	31 OCT 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	99.0 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" 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)

330 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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)

331 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	01 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" 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 type="checkbox"/>
	Mild	<input checked="" 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 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	02 NOV 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	37.6 C
-------------	--------

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

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

Shortness of Breath	None	<input 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 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 NOV 2020
------	-------------

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

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

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

Temperature	101.2 F
-------------	---------

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 type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

342 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	100.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" 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 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

347 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	05 NOV 2020
------	-------------

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

O2 Saturation	92 %
---------------	------

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

Temperature	100.4 F
-------------	---------

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

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

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" 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)

350 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	06 NOV 2020
------	-------------

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

O2 Saturation	93 %
---------------	------

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

Temperature	101.0 F
-------------	---------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

354 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	87 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 NOV 2020
------	------------

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

O2 Saturation	95 %
---------------	------

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 NOV 2020
------	------------

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

O2 Saturation	85 %
---------------	------

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

Temperature	98.6 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

366 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 NOV 2020
------	-------------

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

O2 Saturation	89 %
---------------	------

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

Temperature	98.6 F
-------------	--------

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

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

Shortness of Breath	None <input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

378 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 NOV 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	98.6 F
-------------	--------

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

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

Shortness of Breath	None <input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

382 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

386 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 NOV 2020
------	-------------

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

O2 Saturation	93 %
---------------	------

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

Temperature	98.4 F
-------------	--------

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

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

Shortness of Breath	None	<input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

390 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 NOV 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 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

394 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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	96 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 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)

399 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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	96 %
---------------	------

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

Temperature	98.4 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

402 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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	96 %
---------------	------

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

Temperature	98.6 F
-------------	--------

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

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

Shortness of Breath	None	<input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

406 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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	98 %
---------------	------

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

Temperature	98.3 F
-------------	--------

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

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

Shortness of Breath	None	<input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

410 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 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)

411 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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	99 %
---------------	------

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

Temperature	99.0 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)

414 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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	98 %
---------------	------

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

Temperature	98.6 F
-------------	--------

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

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

Shortness of Breath	None <input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

418 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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 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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

422 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

426 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input checked="" type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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	97.7 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

430 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input checked="" type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	26 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 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)

434 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input checked="" type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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	99 %
---------------	------

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

Temperature	98.0 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)

438 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input checked="" type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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	99 %
---------------	------

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

Temperature	98.3 F
-------------	--------

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

Cough	None <input 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)

442 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input checked="" type="checkbox"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	08 DEC 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

446 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

	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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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"/>

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Date of Visit	02 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	02 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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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 5 NOV 2020
End Date 15 NOV 2020
Oxygen Saturation 85 %

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 _____

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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)

451 of 3760

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	04 NOV 2020
Day 5	Yes	6 NOV 2020
Day 7	Yes	8 NOV 2020
Day 9	Yes	10 NOV 2020
Day 14	Yes	17 NOV 2020
Day 21	Yes	24 NOV 2020
Day 28	Yes	30 NOV 2020

US3272195

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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

Visit date (dd MMM yyyy)	02 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
------------	--------

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 NOV 2020
Time of assessment (00:00-23:59)	13:24 (24 HR)
Vital Signs Date and Time (derived)	02 NOV 2020 13:24
Height (xxx.x)	154 cm
Weight (xxx.x)	74.8 kg
Temperature (xxx.x)	37.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272195

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 NOV 2020

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

US3272195

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

02 NOV 2020

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 NOV 2020
Time of assessment (00:00-23:59)	16:28 (24 HR)
Vital Signs Date and Time (derived)	30 NOV 2020 16:28
Height (xxx.x)	152.5 cm
Weight (xxx.x)	75.0 kg
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 NOV 2020

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

US3272195

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 29 Apr 2021 22:22:50

Generated On: 09 Jun 2021 16:23:03

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 NOV 2020

US3272195

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

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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
------------	---------------

US3272195

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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

US3272195

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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

US3272195

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	16:06 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 16:06
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3272195

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	17:31 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 17:31
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3272195

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

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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.

US3272195

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

Form: Pregnancy Test

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	14 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3272195

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

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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) 16:56 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 16:56

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

US3272195

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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)	15:52 (24 HR)
Collection date and time (derived)	14 JAN 2021 15:52

US3272195

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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)	15:56
Collection Date and Time (derived)	14 JAN 2021 15:56

US3272195

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

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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

Visit date (dd MMM yyyy)	16 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
------------	-------

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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)	16 FEB 2021
Time of assessment (00:00-23:59)	16:35 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 16:35
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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)	16 FEB 2021
Time of assessment (00:00-23:59)	17:34 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 17:34
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3272195

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 FEB 2021

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

US3272195

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	16 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3272195

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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) 16 FEB 2021

What was the treatment time? (00:00-23:59) 16:56 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 16:56

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

US3272195

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272195

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:23:13

Generated On: 09 Jun 2021 16:23:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272195

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	14:39 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 14:39
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272195

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

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

US3272195

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

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

Collection date (dd MMM yyyy)	30 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	14:43 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	30 MAR 2021 14:43
------------------------------------	-------------------

US3272195

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

AEID	USA-US070-2020-MRNA-1273-P30 1000015
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	30 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	07 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	12 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

490 of 3760

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

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	

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

PARTICIPANT WAS EXPOSED TO COWORKER WITH COVID-19 AND TESTED POSITIVE 01NOV2020 AS DID HER FAMILY MEMBERS. OXYGEN SATURATIONS ARE IN THE UPPER 80S AND PRESENTED TO THE ED. DIAGNOSED WITH ACUTE HYPOXIC RESPIRATORY FAILURE REQUIRING SUPPLEMENTAL OXYGEN UP TO 3L/NC. HER CHEST X-RAY ON 7NOV2020 SHOWED MULTIFOCAL PNEUMONIA. SHE WAS GIVEN DEXAMETHASONE, AZITHROMYCIN 500 MG IV Q24HOUR, BRONCHODILATOR TREATMENT, ACETAMINOPHEN, IBUPROFEN, AND REMDESEVIR. HYPOKALEMIA WAS FOUND INCIDENTALLY DURING HER HOSPITALIZATION AND SHE WAS STARTED ON POTASSIUM CHLORIDE AS WELL.

PARTICIPANT REMAINED ON A NON-ICU FLOOR UNTIL DISCHARGE ON 12NOV2020. SENT HOME ON ROOM AIR WITH PRESCRIPTIONS FOR AZITHROMYCIN 250 MG TABLET- 500 MG ON DAY ONE AND THEN 250 MG TABLET ON DAYS 2-5, DEXAMETHASONE 6 MG ONCE DAILY X 4 DAYS, AND POTASSIUM CHLORIDE 10 MEQ BID X 7 DAYS. SHE WAS SET TO FOLLOW UP WITH HER PRIMARY CARE PHYSICIAN IN 3-5 DAYS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

PRODUCTION RELEASE (v12.003 EAB) (1725)	492 of 3760
---	-------------

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **09 Apr 2021 15:02:36**

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#) 0

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

AEID	USA-US070-2020-MRNA-1273-P30 1000015
Adverse event	PNEUMONIA DUE TO COVID-19 VIRUS
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)	7 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)	30 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	07 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	12 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	494 of 3760

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

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	

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

SUBJECT ADMITTED TO
HOSPITAL ON 07NOV2020 DUE
ACUTE RESPIRATORY FAILURE
DUE TO COVID-19 AND
PNEUMONIA DUE TO COVID-19
VIRUS.

PARTICIPANT WAS EXPOSED
TO COWORKER WITH COVID-19
AND TESTED POSITIVE
01NOV2020 AS DID HER FAMILY
MEMBERS. OXYGEN
SATURATIONS ARE IN THE
UPPER 80S AND PRESENTED TO
THE ED. DIAGNOSED WITH
ACUTE HYPOXIC RESPIRATORY
FAILURE REQUIRING
SUPPLEMENTAL OXYGEN UP
TO 3L/NC. HER CHEST X-RAY
ON 7NOV2020 SHOWED
MULTIFOCAL PNEUMONIA- NO
REPEAT X-RAY. SHE WAS
GIVEN DEXAMETHASONE,
AZITHROMYCIN 500 MG IV
Q24HOUR, BRONCHODILATOR
TREATMENT,
ACETAMINOPHEN, IBUPROFEN,
AND REMDESEVIR.

PARTICIPANT REMAINED ON A
NON-ICU FLOOR UNTIL
DISCHARGE ON 12NOV2020.
SENT HOME ON ROOM AIR
WITH PRESCRIPTIONS FOR
AZITHROMYCIN 250 MG

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

TABLET- 500 MG ON DAY ONE
AND THEN 250 MG TABLET ON
DAYS 2-5, DEXAMETHASONE 6
MG ONCE DAILY X 4 DAYS,
AND POTASSIUM CHLORIDE 10
MEQ BID X 7 DAYS. SHE WAS
SET TO FOLLOW UP WITH HER
PRIMARY CARE PHYSICIAN IN
3-5 DAYS. RESPIRATORY
SYMPTOMS RESOLVED
30NOV2020 WITH PNEUMONIA
RESOLUTION.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

AEID	USA-US070-2020-MRNA-1273-P30 1000015
Adverse event	HYPOXIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	07 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 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	07 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	12 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

498 of 3760

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

Number of Days in ICU	0
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	

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

SUBJECT ADMITTED TO HOSPITAL ON 07NOV2020 DUE TO WORSENING SYMPTOMS OF COVID 19 POSITIVE ILLNESS WITH SECONDARY PNEUMONIA THAT BEGAN BEING TREATED IN PATIENT 07NOV2020. SHE WAS ALSO GIVEN SUPPLEMENTAL OXYGEN DUE TO HYPOXIA.

PARTICIPANT WAS EXPOSED TO COWORKER WITH COVID-19 AND TESTED POSITIVE 01NOV2020 AS DID HER FAMILY MEMBERS. OXYGEN SATURATIONS ARE IN THE UPPER 80S AND PRESENTED TO THE ED. DIAGNOSED WITH ACUTE HYPOXIC RESPIRATORY FAILURE REQUIRING SUPPLEMENTAL OXYGEN UP TO 3L/NC. HER CHEST X-RAY ON 7NOV2020 SHOWED MULTIFOCAL PNEUMONIA. SHE WAS GIVEN DEXAMETHASONE, AZITHROMYCIN 500 MG IV Q24HOUR, BRONCHODILATOR TREATMENT, ACETAMINOPHEN, IBUPROFEN, AND REMDESEVIR. HYPOKALEMIA WAS FOUND INCIDENTALLY DURING HER HOSPITALIZATION AND SHE WAS STARTED ON POTASSIUM

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

CHLORIDE AS WELL.

PARTICIPANT REMAINED ON A
NON-ICU FLOOR UNTIL
DISCHARGE ON 12NOV2020.
SENT HOME ON ROOM AIR
WITH PRESCRIPTIONS FOR
AZITHROMYCIN 250 MG
TABLET- 500 MG ON DAY ONE
AND THEN 250 MG TABLET ON
DAYS 2-5, DEXAMETHASONE 6
MG ONCE DAILY X 4 DAYS,
AND POTASSIUM CHLORIDE 10
MEQ BID X 7 DAYS. SHE WAS
SET TO FOLLOW UP WITH HER
PRIMARY CARE PHYSICIAN IN
3-5 DAYS.

SHE IS RECOVERED.
PRESENTED FOR DAY 28
CONVALESCENT VISIT ON
30NOV2020. LUNGS CLEAR TO
AUSCULTATION, BREATHING
WITHOUT EFFORT, NO
SUPPLEMENTAL O2, NO
RESPIRATORY, PNEUMONIA,
OR COVID MEDICATIONS, NO
RESPIRATORY SYMPTOMS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

AEID	
Adverse event	WORSENING ACID INDIGESTION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

502 of 3760

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

AEID

Adverse event

VAGINAL CANDIDIASIS

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)

15 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)

20 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

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

504 of 3760

EAB) (1725)

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

AEID

Adverse event

HYPOKALEMIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

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

506 of 3760

EAB) (1725)

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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	

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

HYPOKALEMIA WAS AN
INCIDENTAL FINDING ON THE
PARTICIPANTS ADMISSION TO
THE HOSPITAL FOR COVID
CAUSED HYPOXIA. THE
HYPOKALEMIA WAS NOT
SYMPTOMATIC. THE TREATING
PHYSICIAN DID NOT MAKE A
DETERMINATION AS TO THE
CAUSE OF THE HYPOKALEMIA.
PARTICIPANT WAS DISMISSED
FROM THE HOSPITAL DUE TO
RESOLUTION OF HYPOXIA ON
12NOV2020. SHE WAS GIVEN A
ONE WEEK PRESCRIPTION FOR
POTASSIUM CHLORIDE 10 MEQ
BID X 7 DAYS. THE
PARTICIPANT FINISHED HER
PRESCRIPTION ON 19NOV2020.
RESOLVED 20NOV2020.

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

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

Yes ☒

No ☐

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

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication ALLEGRA-D

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 120/60

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

510 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN APR 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 OCT 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"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED LUMBAR
BACKACHE

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

512 of 3760

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify SPRAY

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

514 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

516 of 3760

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication COVID 19

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)

518 of 3760

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication ELDERBERRY WITH ZINC

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

520 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 DEC 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
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="radio"/>	

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 4000

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

522 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 846

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

524 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)	30 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication ROCEPHIN (CEFTRIAXONE)

Prophylaxis Yes ☐
No ☒

Indication SECONDARY PNEUMONIA DUE
TO COVID 19 POSITIVE ILLNESS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

526 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication SUPPLEMENTAL OXYGEN

Prophylaxis Yes ☐
No ☒

Indication HYPOXIA

Dose per administration 3

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

If dose unit is Other, specify LITERS

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 CONTINUOUS

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

PRODUCTION RELEASE (v12.003

528 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

530 of 3760

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)	02 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

532 of 3760

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)	02 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication DECADRON
(DEXAMETHASONE)

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

534 of 3760

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)	7 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)	08 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA SECONDARY TO
COVID 19 POSITIVE ILLNESS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

536 of 3760

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	7 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 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"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication REMDESIVIR

Prophylaxis Yes ☐
No ☒

Indication COVID 19

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)

538 of 3760

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	7 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 7 NOV 2020		
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"/>	

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication REMDESIVIR

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

540 of 3760

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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 checked="" 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)	8 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)	11 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"/>	

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication LOVENOX

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

542 of 3760

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)	7 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)		08 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication CONVALESCENT PLASMA

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 1

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

If dose unit is Other, specify UNIT (APPROX 200ML)

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

544 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		9 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA SECONDARY TO
COVID 19 ILLNESS.

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

546 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)		12 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication POTASSIUM

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 10

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

548 of 3760

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication CALCIUM CARBONATE

Prophylaxis Yes ☐
No ☒

Indication ACID INDIGESTION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

550 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1992	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication CETIRIZINE

Prophylaxis Yes ☐
No ☒

Indication NASAL CONGESTION,
ALLERGIES - COVID 19

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

552 of 3760

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)		15 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication FLUCONAZOLE

Prophylaxis Yes ☐
No ☒

Indication VAGINAL CANDIDIASIS

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

554 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)	16 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)		16 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"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACID INDIGESTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

556 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

Name of Medication ALBUTEROL INHALER

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 180

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

If dose unit is Other, specify MCG

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

558 of 3760

EAB) (1725)

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 14 Apr 2021 19:02:48

Generated On: 09 Jun 2021 16:23:03

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	08 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3272195

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 15:02:39

Generated On: 09 Jun 2021 16:23:03

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3272195

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 15:02:36

Generated On: 09 Jun 2021 16:23:03

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
07 NOV 2020	CHEST X-RAY	Adverse Event	

US3272195

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:23:03

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

US3272195

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:23:03

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 ☐

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

SAEID	USA-US070-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

SAEID	USA-US070-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	09/NOV/2020 17:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

SAEID	USA-US070-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	10/NOV/2020 15:37
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

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

SAEID	USA-US070-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	11/NOV/2020 20:29
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

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

SAEID	USA-US070-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	13/NOV/2020 20:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

SAEID	USA-US070-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	23/NOV/2020 15:22
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

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

SAEID	USA-US070-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	02/DEC/2020 13:55
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

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

SAEID	USA-US070-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	11/DEC/2020 13:52
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

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

SAEID	USA-US070-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	14/DEC/2020 11:01
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

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (9)

Data signed: (b) (4) 29 Apr 2021 22:22:52

Generated On: 09 Jun 2021 16:23:03

SAEID	USA-US070-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	21/DEC/2020 15:07
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

US3272195 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272195

Form: Participant Creation

Generated On: 09 Jun 2021 16:23:03

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:27:45
User entered 'US3272195'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 23:34:10

US3272195

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:29:07
User entered 'Yes (Y)'		20 Aug 2020 00:20:27

US3272195

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:29:07
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 23:34:11

US3272195

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:29:07
User entered 'Clinic (Clinic)'		20 Aug 2020 00:20:27

US3272195

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'SCRN'	System	20 Aug 2020 00:20:27

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered (b) (6) 1976'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 23:34:12

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered '44'		20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'YEARS'	System	20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered '44'	System	20 Aug 2020 00:09:00

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered 'Female (F)'		20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'		20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered 'l'		20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered '0'		20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered '0'		20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered '0'		20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered '0'		20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered '0'		20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered empty.		20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered '0'		20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:23:03

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:19
User entered '0'		20 Aug 2020 00:20:57

US3272195

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:03

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:26
User entered '19 Aug 2020'	Kayla Flege (b) (4) (b) (4)	20 Aug 2020 00:09:00

US3272195

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'Aug 2020'	System	20 Aug 2020 00:09:00

US3272195

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered '2020'	System	20 Aug 2020 00:09:00

US3272195

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:26
User entered 'Amendment 2 (2)'	Kayla Flege (b) (4) (b) (4)	20 Aug 2020 00:09:00

US3272195

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:26
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	20 Aug 2020 00:09:00

US3272195

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:26
User entered empty.	Kayla Flege (b) (4)	20 Aug 2020 00:09:00
	(b) (4)	

US3272195

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:26
User entered empty.	Kayla Flege (b) (4) (b) (4)	20 Aug 2020 00:09:00

US3272195

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:26
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	20 Aug 2020 00:09:00

US3272195

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:26
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 23:34:11

US3272195

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:23:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'I'	System	20 Aug 2020 00:09:05

US3272195

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:30:30
User entered 'Yes (Y)'	Kayla Flege (b) (4)	20 Aug 2020 00:09:05
	(b) (4)	

US3272195

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:23:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:31:05
User entered 'Yes (Y)'		20 Aug 2020 00:21:33

US3272195

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
User closed query 'There was an addition of gestational diabetes added to the source. Should this also be added in the medical history? Review and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 15:45:26
Query 'There was an addition of gestational diabetes added to the source. Should this also be added in the medical history? Review and update if applicable.' answered with 'UPDATED' (Site from CRA).		16 Sep 2020 22:41:48
User opened query 'There was an addition of gestational diabetes added to the source. Should this also be added in the medical history? Review and update if applicable.' (Site from CRA).		16 Sep 2020 16:34:49
DataPoint Verified.		16 Sep 2020 16:31:18
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 00:23:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 00:23:11
Data point term sent to Coder	System	20 Aug 2020 00:22:50
User entered 'seasonal allergies'	(b) (4), (b) (6)	20 Aug 2020 00:22:00

US3272195

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:31:18
User entered 'UN UNK 2007'		20 Aug 2020 00:22:00

US3272195

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:31:18
User entered '0'		20 Aug 2020 00:22:00

US3272195

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:31:18
User entered 'Yes (Y)'		20 Aug 2020 00:22:00

US3272195

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:31:18
User entered empty.		20 Aug 2020 00:22:00

US3272195

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:31:18
User entered '0'		20 Aug 2020 00:22:00

US3272195

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'Jan 2007'	System	20 Aug 2020 00:22:00

US3272195

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered '2007'	System	20 Aug 2020 00:22:00

US3272195

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered empty.	System	20 Aug 2020 00:22:00

US3272195

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered empty.	System	20 Aug 2020 00:22:00

US3272195

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:31:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Lumbar pain - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 07:26:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 07:26:19
Data point term sent to Coder	System	20 Aug 2020 00:22:50
User entered 'generalized lumbar backache'	(b) (4), (b) (6)	20 Aug 2020 00:22:23

US3272195

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:31:18
User entered 'UN UNK 2019'		20 Aug 2020 00:22:23

US3272195

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:31:18
User entered '0'		20 Aug 2020 00:22:23

US3272195

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:31:18
User entered 'Yes (Y)'		20 Aug 2020 00:22:23

US3272195

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:31:18
User entered empty.		20 Aug 2020 00:22:23

US3272195

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:31:18
User entered '0'		20 Aug 2020 00:22:23

US3272195

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:03

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'Jan 2019'	System	20 Aug 2020 00:22:23

US3272195

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered '2019'	System	20 Aug 2020 00:22:23

US3272195

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered empty.	System	20 Aug 2020 00:22:23

US3272195

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered empty.	System	20 Aug 2020 00:22:23

US3272195

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:23:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:01
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Maternal complications of pregnancy, HLT: Pregnancy complicated by maternal disorders, PT: Gestational diabetes, LLT: Gestational diabetes - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 22:41:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 22:41:52
Data point term sent to Coder	System	16 Sep 2020 22:40:32
User entered 'GESTATIONAL DIABETES'	(b) (4), (b) (6)	16 Sep 2020 22:40:29

US3272195

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:01
User entered 'UN UNK 2007'		16 Sep 2020 22:40:29

US3272195

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:01
User entered '0'		16 Sep 2020 22:40:29

US3272195

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:23:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:01
User entered 'No (N)'		16 Sep 2020 22:40:29

US3272195

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:01
User entered 'UN UNK 2007'		16 Sep 2020 22:40:29

US3272195

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:23:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:01
User entered '0'		16 Sep 2020 22:40:29

US3272195

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'Jan 2007'	System	16 Sep 2020 22:40:29

US3272195

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered '2007'	System	16 Sep 2020 22:40:29

US3272195

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'Jan 2007'	System	16 Sep 2020 22:40:29

US3272195

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered '2007'	System	16 Sep 2020 22:40:29

US3272195

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:23:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:01
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Maternal complications of pregnancy, HLT: Pregnancy complicated by maternal disorders, PT: Gestational diabetes, LLT: Gestational diabetes - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 22:42:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 22:42:52
Data point term sent to Coder	System	16 Sep 2020 22:41:33
User entered 'GESTATIONAL DIABETES'	(b) (4), (b) (6)	16 Sep 2020 22:41:02

US3272195

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:01
User entered 'UN UNK 2008'		16 Sep 2020 22:41:02

US3272195

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:01
User entered '0'		16 Sep 2020 22:41:02

US3272195

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:23:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:01
User entered 'No (N)'		16 Sep 2020 22:41:02

US3272195

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:01
User entered 'UN UNK 2008'		16 Sep 2020 22:41:02

US3272195

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:23:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:01
User entered '0'		16 Sep 2020 22:41:02

US3272195

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'Jan 2008'	System	16 Sep 2020 22:41:02

US3272195

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered '2008'	System	16 Sep 2020 22:41:02

US3272195

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'Jan 2008'	System	16 Sep 2020 22:41:02

US3272195

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered '2008'	System	16 Sep 2020 22:41:02

US3272195

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:23:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:54:57
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:22:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:22:50
Data point term sent to Coder	System	17 Nov 2020 18:21:38
User entered 'sciatica'	(b) (4), (b) (6)	17 Nov 2020 18:21:15

US3272195

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:54:57
User entered 'UN UNK 2017'		17 Nov 2020 18:21:15

US3272195

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:54:57
User entered '0'		17 Nov 2020 18:21:15

US3272195

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:23:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:54:57
User entered 'Yes (Y)'		17 Nov 2020 18:21:15

US3272195

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:54:57
User entered empty.		17 Nov 2020 18:21:15

US3272195

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:23:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:54:57
User entered '0'		17 Nov 2020 18:21:15

US3272195

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'Jan 2017'	System	17 Nov 2020 18:21:15

US3272195

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered '2017'	System	17 Nov 2020 18:21:15

US3272195

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered empty.	System	17 Nov 2020 18:21:15

US3272195

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered empty.	System	17 Nov 2020 18:21:15

US3272195

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:23:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:54:57
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Acid indigestion - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:22:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:22:49
Data point term sent to Coder	System	17 Nov 2020 18:21:38
User entered 'acid indigestion'	(b) (4), (b) (6)	17 Nov 2020 18:21:33

US3272195

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:54:57
User entered 'UN UNK 1992'		17 Nov 2020 18:21:33

US3272195

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:54:57
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:21:33

US3272195

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:23:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:54:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 18:21:33

US3272195

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:54:57
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:21:33

US3272195

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:23:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:54:57
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:21:33

US3272195

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'Jan 1992'	System	17 Nov 2020 18:21:33

US3272195

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered '1992'	System	17 Nov 2020 18:21:33

US3272195

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered empty.	System	17 Nov 2020 18:21:33

US3272195

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered empty.	System	17 Nov 2020 18:21:33

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:17
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:38:50
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 22:42:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:42:46
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:33:00
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 16:50:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:50:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:17
User entered '19 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:42:46
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 16:50:39
User entered empty; reason for change Data Entry Error		16 Sep 2020 16:50:39
DataPoint Verified.		16 Sep 2020 16:36:16
User entered '19 Aug 2020'		20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:17
User entered '17:51' reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:42:46
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 16:50:39
User entered empty; reason for change Data Entry Error		16 Sep 2020 16:50:39
DataPoint Verified.		16 Sep 2020 16:36:16
User entered '17:51'		20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered '19 Aug 2020 17:51'	System	25 Sep 2020 22:42:46
User entered empty.	System	16 Sep 2020 16:50:39
User entered '19 Aug 2020 17:51'	System	20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:17
User entered '152.5' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:42:46
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 16:50:39
User entered empty; reason for change Data Entry Error		16 Sep 2020 16:50:39
DataPoint Verified.		16 Sep 2020 16:36:16
User entered '152.5' cm		20 Aug 2020 00:23:25
DataPoint set to visible.	System	20 Aug 2020 00:09:05

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:17
User entered '78' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:42:46
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 16:50:39
User entered empty; reason for change Data Entry Error		16 Sep 2020 16:50:39
DataPoint Verified.		16 Sep 2020 16:36:16
User entered '78' kg		20 Aug 2020 00:23:25
DataPoint set to visible.	System	20 Aug 2020 00:09:05

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered '33.53937'	System	25 Sep 2020 22:42:46
User entered empty.	System	16 Sep 2020 16:50:39
User entered '33.5'	System	20 Aug 2020 00:23:25
DataPoint set to visible.	System	20 Aug 2020 00:09:05

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'kg/m2'	System	25 Sep 2020 22:42:46
User entered empty.	System	16 Sep 2020 16:50:39
User entered 'kg/m2'	System	20 Aug 2020 00:23:25
DataPoint set to visible.	System	20 Aug 2020 00:09:05

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:17
User closed query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:38:53
Query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	25 Sep 2020 22:42:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:42:46
User opened query 'Per CDM Re-Query: Site response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please enter "ND" as instructed. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:33:04
User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:33:04
Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:50:51
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 16:50:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 16:50:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:16

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 21:25:33
User entered '36.4' C	(b) (4), (b) (6)	20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:17
DataPoint Un-verified.		16 Sep 2020 16:50:39
User entered empty; reason for change Data Entry Error		16 Sep 2020 16:50:39
DataPoint Verified.		16 Sep 2020 16:36:16
User entered 'Oral (Oral)'		20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:16
User entered empty.		20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:42:46
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 16:50:39
User entered empty; reason for change Data Entry Error		16 Sep 2020 16:50:39
DataPoint Verified.		16 Sep 2020 16:36:16
User entered '77'		20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'bpm'	System	25 Sep 2020 22:42:46
User entered empty.	System	16 Sep 2020 16:50:39
User entered 'bpm'	System	20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:42:46
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 16:50:39
User entered empty; reason for change Data Entry Error		16 Sep 2020 16:50:39
DataPoint Verified.		16 Sep 2020 16:36:16
User entered '16'		20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'breaths/min'	System	25 Sep 2020 22:42:46
User entered empty.	System	16 Sep 2020 16:50:39
User entered 'breaths/min'	System	20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:42:46
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 16:50:39
User entered empty; reason for change Data Entry Error		16 Sep 2020 16:50:39
DataPoint Verified.		16 Sep 2020 16:36:16
User entered '129'		20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'mmHg'	System	25 Sep 2020 22:42:46
User entered empty.	System	16 Sep 2020 16:50:39
User entered 'mmHg'	System	20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:49:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	25 Sep 2020 22:42:46
DataPoint Un-verified.	(b) (4), (b) (6)	16 Sep 2020 16:50:39
User entered empty; reason for change Data Entry Error		16 Sep 2020 16:50:39
DataPoint Verified.		16 Sep 2020 16:36:16
User entered '86'		20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered 'mmHg'	System	25 Sep 2020 22:42:46
User entered empty.	System	16 Sep 2020 16:50:39
User entered 'mmHg'	System	20 Aug 2020 00:23:25

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33

US3272195

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33

US3272195

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:26
User entered 'Yes (Y)'		20 Aug 2020 00:23:48

US3272195

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:26
User entered '19 Aug 2020'		20 Aug 2020 00:23:48

US3272195

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:23:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:29
User entered '19 Aug 2020'		20 Aug 2020 00:25:03

US3272195

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:23:03

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:29
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	20 Aug 2020 00:26:31
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	20 Aug 2020 00:25:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 00:25:03

US3272195

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:23:03

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:29
User entered empty; reason for change Data Entry Error		20 Aug 2020 00:26:31
User entered 'Partner medically sterile (PARTNER STERILE)'		20 Aug 2020 00:25:03

US3272195

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:23:03

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:29
User entered empty; reason for change Data Entry Error		20 Aug 2020 00:26:31
User entered 'Male partner vasectomy un/unk/2010'		20 Aug 2020 00:25:03

US3272195

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:29
User entered empty.		20 Aug 2020 00:25:03

US3272195

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:23:03

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:29
User entered '0'		20 Aug 2020 00:25:03

US3272195

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:29
User entered empty.		20 Aug 2020 00:25:03

US3272195

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:23:03

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:29
User entered '0'		20 Aug 2020 00:25:03

US3272195

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:35
User entered 'Yes (Y)'		20 Aug 2020 00:27:29

US3272195

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:35
User entered '19 Aug 2020'		20 Aug 2020 00:27:29

US3272195

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:35
User entered 'Urine (URINE)'		20 Aug 2020 00:27:29

US3272195

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:35
User entered 'Negative (NEGATIVE)'		20 Aug 2020 00:27:29

US3272195

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:35
User entered 'No (N)'		20 Aug 2020 00:27:29

US3272195

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:35
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 09:29:27
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' answered with 'confirm update' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 20:40:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 20:40:02
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 21:56:52
User entered '19 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 00:27:29

US3272195

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:36:35
User entered empty; reason for change Data Entry Error		09 Sep 2020 20:40:02
User entered '18:19'		20 Aug 2020 00:27:29

US3272195

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User entered empty.	System	09 Sep 2020 20:40:02
User entered '19 Aug 2020 18:19'	System	20 Aug 2020 00:27:29

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'Yes (Y)'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'No (N)'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'No (N)'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'No (N)'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'No (N)'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'No (N)'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'No (N)'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'No (N)'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'No (N)'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'No (N)'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'No (N)'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'No (N)'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered empty.		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered '0'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered '0'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered '0'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered 'l'		20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 00:27:54

US3272195

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:23:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:39:33
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:41
User entered empty.		20 Aug 2020 00:27:54

US3272195

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:13
User entered 'Yes (Y)'		20 Aug 2020 00:28:17

US3272195

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:13
User entered '19 Aug 2020'		20 Aug 2020 00:28:17

US3272195

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:13
User entered 'Clinic (Clinic)'		20 Aug 2020 00:28:17

US3272195

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User entered 'VISIT1'	System	20 Aug 2020 00:28:17

US3272195

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:16
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 23:39:19

US3272195

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:03

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:16
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:45:11
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:45:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 23:39:19
User entered '105994' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 23:39:19

US3272195

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:16
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 23:39:19

US3272195

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:03

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)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:16
User entered 'No (N)'		20 Aug 2020 00:28:43

US3272195

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:03

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)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:16
User entered 'No (N)'		20 Aug 2020 00:28:43

US3272195

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:16
User entered 'No (N)'		20 Aug 2020 00:28:43

US3272195

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:03

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:16
User entered 'No (N)'		20 Aug 2020 00:28:43

US3272195

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:16
User entered 'No (N)'		20 Aug 2020 00:28:43

US3272195

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:23:03

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:10
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 21:34:33
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:28
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:39:25

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:22:09
DataPoint Un-verified.	Ashley Bell (b) (4)	12 Nov 2020 01:06:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	12 Nov 2020 01:06:07
User closed query 'Per CDM Re-Query: response of 'updated' is noted; however, unit is still present. Please remove from both Height and Weight.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 02:01:32
Query 'Per CDM Re-Query: response of 'updated' is noted; however, unit is still present. Please remove from both Height and Weight.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	10 Nov 2020 20:19:45
User opened query 'Per CDM Re-Query: response of 'updated' is noted; however, unit is still present. Please remove from both Height and Weight.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 11:06:10
User closed query 'Per CDM: Response noted kindly remove cm. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 11:06:10
Query 'Per CDM: Response noted kindly remove cm. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Nov 2020 21:38:41
User opened query 'Per CDM: Response noted kindly remove cm. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 17:53:16
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:31:17
Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	04 Sep 2020 00:29:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:29:19
User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:18:45

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

Height

Audit	User	Time (GMT)
User entered '152.5' cm	(b) (4), (b) (6)	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:22:09
DataPoint Un-verified.	Ashley Bell (b) (4)	12 Nov 2020 01:06:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	12 Nov 2020 01:06:07
User closed query 'Per CDM: Response noted kindly remove kg.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 11:06:13
Query 'Per CDM: Response noted kindly remove kg.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Nov 2020 21:38:47
User opened query 'Per CDM: Response noted kindly remove kg.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 17:54:37
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:29:19
User entered '78' kg	(b) (4), (b) (6)	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:22:09
DataPoint Un-verified.	Ashley Bell (b) (4)	12 Nov 2020 01:06:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	12 Nov 2020 01:06:07
User closed query 'Per CDM Re-Query: response of 'updated' is noted; however, unit is still present. Please remove from both Height and Weight.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 02:01:32
Query 'Per CDM Re-Query: response of 'updated' is noted; however, unit is still present. Please remove from both Height and Weight.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	10 Nov 2020 20:19:45
User opened query 'Per CDM Re-Query: response of 'updated' is noted; however, unit is still present. Please remove from both Height and Weight.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 11:06:10
User closed query 'Per CDM: Response noted kindly remove cm.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 11:06:10
Query 'Per CDM: Response noted kindly remove cm.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Nov 2020 21:38:41
User opened query 'Per CDM: Response noted kindly remove cm.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 17:53:16
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:31:17
Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	04 Sep 2020 00:29:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:29:19
User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:18:45

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

Height

Audit	User	Time (GMT)
User entered '152.5' cm	(b) (4), (b) (6)	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:22:09
DataPoint Un-verified.	Ashley Bell (b) (4)	12 Nov 2020 01:06:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	12 Nov 2020 01:06:07
User closed query 'Per CDM: Response noted kindly remove kg.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 11:06:13
Query 'Per CDM: Response noted kindly remove kg.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Nov 2020 21:38:47
User opened query 'Per CDM: Response noted kindly remove kg.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 17:54:37
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:29:19
User entered '78' kg	(b) (4), (b) (6)	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User accepted default value 'Pre-Dose (PREDOSE)'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered 'Yes (Y)'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '19 Aug 2020'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '17:51'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User entered '19 Aug 2020 17:51'	System	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '36.4' C		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered 'Oral (Oral)'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered empty.		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '77'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User entered 'bpm'	System	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '16'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User entered 'breaths/min'	System	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '129'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User entered 'mmHg'	System	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '86'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User entered 'mmHg'	System	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:22:09
DataPoint Un-verified.	Ashley Bell (b) (4)	12 Nov 2020 01:06:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	12 Nov 2020 01:06:07
User closed query 'Per CDM Re-Query: response of 'updated' is noted; however, unit is still present. Please remove from both Height and Weight.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 02:01:32
Query 'Per CDM Re-Query: response of 'updated' is noted; however, unit is still present. Please remove from both Height and Weight.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	10 Nov 2020 20:19:45
User opened query 'Per CDM Re-Query: response of 'updated' is noted; however, unit is still present. Please remove from both Height and Weight.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 11:06:10
User closed query 'Per CDM: Response noted kindly remove cm. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 11:06:10
Query 'Per CDM: Response noted kindly remove cm. ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Nov 2020 21:38:41
User opened query 'Per CDM: Response noted kindly remove cm. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 17:53:16
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User closed query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:31:17
Query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	04 Sep 2020 00:29:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:29:19
User opened query 'Per CDM: Per CCG, Pages 15-16, Height and Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:18:45

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

Height

Audit	User	Time (GMT)
User entered '152.5' cm	(b) (4), (b) (6)	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:22:09
DataPoint Un-verified.	Ashley Bell (b) (4)	12 Nov 2020 01:06:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	12 Nov 2020 01:06:07
User closed query 'Per CDM: Response noted kindly remove kg.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 11:06:13
Query 'Per CDM: Response noted kindly remove kg.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Nov 2020 21:38:47
User opened query 'Per CDM: Response noted kindly remove kg.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 17:54:37
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	04 Sep 2020 00:29:19
User entered '78' kg	(b) (4), (b) (6)	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User accepted default value 'Post-Dose (POSTDOSE)'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered 'Yes (Y)'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '19 Aug 2020'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 05:45:08
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		20 Aug 2020 00:49:16
User entered '19:32'	(b) (4), (b) (6)	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User entered '19 Aug 2020 19:32'	System	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '37.1' C		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered 'Other (Other)'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered 'temporal'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '67'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User entered 'bpm'	System	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '14'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User entered 'breaths/min'	System	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '123'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User entered 'mmHg'	System	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:29
User entered '86'		20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:52:12
User entered 'mmHg'	System	20 Aug 2020 00:49:16

US3272195

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:37
User entered 'Yes (Y)'		20 Aug 2020 00:49:42

US3272195

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:37
User entered '19 Aug 2020'		20 Aug 2020 00:49:42

US3272195

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:41
User closed query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' (Site from DM).		16 Sep 2020 12:28:33
Query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' answered with 'confirm update' (Site from DM).		09 Sep 2020 20:40:25
User entered 'No (N)' reason for change: Data Entr Error		09 Sep 2020 20:40:21
User opened query 'Per CDM: Screening and dosing on the same day. Field should be marked No. Please review page and update accordingly with CCG's' (Site from DM).		02 Sep 2020 21:56:39
User entered 'Yes (Y)'		20 Aug 2020 00:51:30

US3272195

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:41
Query 'Data is required. Please provide.' canceled (Site from System).		02 Sep 2020 21:56:36
User opened query 'Data is required. Please provide.' System (Site from System).		20 Aug 2020 00:51:30
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 00:51:30

US3272195

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:41
User entered empty; reason for change Data Entry Error		09 Sep 2020 20:40:21
User entered 'Urine (URINE)'		20 Aug 2020 00:51:30

US3272195

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:41
User entered empty; reason for change Data Entry Error		09 Sep 2020 20:40:21
User entered 'Negative (NEGATIVE)'		20 Aug 2020 00:51:30

US3272195

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:41
User entered 'No (N)'		20 Aug 2020 00:51:30

US3272195

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:41
User entered empty; reason for change Data Entry Error		09 Sep 2020 20:40:21
User entered '19 Aug 2020'		20 Aug 2020 00:51:30

US3272195

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:41
User entered empty; reason for change Data Entry Error		09 Sep 2020 20:40:21
User entered '17:45'		20 Aug 2020 00:51:30

US3272195

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User entered empty.	System	09 Sep 2020 20:40:21
User entered '19 Aug 2020 17:45'	System	20 Aug 2020 00:51:30

US3272195

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:48
User entered 'Yes (Y)'	Kayla Flege (b) (4)	20 Aug 2020 00:09:27
	(b) (4)	

US3272195

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:48
User entered empty.	Kayla Flege (b) (4) (b) (4)	20 Aug 2020 00:09:27

US3272195

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

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)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:48
User entered empty.	Kayla Flege (b) (4) (b) (4)	20 Aug 2020 00:09:27

US3272195

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 00:09:27

US3272195

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:48
User entered '19 Aug 2020'	Kayla Flege (b) (4)	20 Aug 2020 00:09:27
	(b) (4)	

US3272195

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:48
User entered '19:01'	Kayla Flege (b) (4)	20 Aug 2020 00:09:27
	(b) (4)	

US3272195

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User entered '19 Aug 2020 19:01'	System	20 Aug 2020 00:09:27

US3272195

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:48
User entered 'Left Arm (LEFT ARM)'	Kayla Flege (b) (4) (b) (4)	20 Aug 2020 00:09:27

US3272195

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
DataPoint Verified.		16 Sep 2020 16:37:48
User entered 'ONCE'	System	20 Aug 2020 00:09:27

US3272195

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 00:09:27

US3272195

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:52
User entered 'Yes (Y)'		20 Aug 2020 00:52:06

US3272195

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:52
User entered '19 Aug 2020'		20 Aug 2020 00:52:06

US3272195

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:52
User entered '18:19'		20 Aug 2020 00:52:06

US3272195

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User entered '19 Aug 2020 18:19'	System	20 Aug 2020 00:52:06

US3272195

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:23:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:56
User entered '19 Aug 2020'		20 Aug 2020 00:52:39

US3272195

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		20 Aug 2020 00:52:39

US3272195

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:56
User entered 'Yes (Y)'		20 Aug 2020 00:52:39

US3272195

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:56
User entered '18:13'		20 Aug 2020 00:52:39

US3272195

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User entered '19 Aug 2020 18:13'	System	20 Aug 2020 00:52:39

US3272195

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		20 Aug 2020 00:52:39

US3272195

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:56
User entered 'No (N)'		20 Aug 2020 00:52:39

US3272195

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:37:56
User entered empty.		20 Aug 2020 00:52:39

US3272195

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User entered empty.	System	20 Aug 2020 00:52:39

US3272195

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:38:00
User entered 'Yes (Y)'		20 Aug 2020 00:52:44

US3272195

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:51:48
User entered 'I'	System	20 Aug 2020 00:52:44

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:37:48', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '5590b7bb-a095-4bb6-a4b3-c0776e2e3d5c'	System	20 Aug 2020 00:38:17
User entered 'Yes (Y)'	System	20 Aug 2020 00:38:17

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:37:53', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '5590b7bb-a095-4bb6-a4b3-c0776e2e3d5c'	System	20 Aug 2020 00:38:17
User entered '98.7'	System	20 Aug 2020 00:38:17

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:38:03', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '5590b7bb-a095-4bb6-a4b3-c0776e2e3d5c'	System	20 Aug 2020 00:38:17
User entered 'No (N)'	System	20 Aug 2020 00:38:17

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:38:13', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '5590b7bb-a095-4bb6-a4b3-c0776e2e3d5c'	System	20 Aug 2020 00:38:17
User entered '19 Aug 2020 19:38'	System	20 Aug 2020 00:38:17

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Aug 2020 19:21'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Aug 2020 21:51'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:41:23', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b8712b60-e33b-4517-a711-b46bd354a842'	System	20 Aug 2020 13:42:11
User entered 'Yes (Y)'	System	20 Aug 2020 13:42:11

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:41:28', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b8712b60-e33b-4517-a711-b46bd354a842'	System	20 Aug 2020 13:42:11
User entered '98.2'	System	20 Aug 2020 13:42:11

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:41:42', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b8712b60-e33b-4517-a711-b46bd354a842'	System	20 Aug 2020 13:42:11
User entered 'Yes (Y)'	System	20 Aug 2020 13:42:11

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
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 'took meds for mh not vaccine' (Site from System).		16 Sep 2020 17:35:23
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:41:49', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b8712b60-e33b-4517-a711-b46bd354a842'	System	20 Aug 2020 13:42:11
User entered '1'	System	20 Aug 2020 13:42:11

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:41:49', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b8712b60-e33b-4517-a711-b46bd354a842'	System	20 Aug 2020 13:42:11
User entered '0'	System	20 Aug 2020 13:42:11

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:42:06', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b8712b60-e33b-4517-a711-b46bd354a842'	System	20 Aug 2020 13:42:11
User entered '20 Aug 2020 08:42'	System	20 Aug 2020 13:42:11

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Aug 2020 22:46'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '20 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 2'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:05:07', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '650c997e-05b2-41ef-bede-c2f384bc6e00'	System	21 Aug 2020 00:05:29
User entered 'Yes (Y)'	System	21 Aug 2020 00:05:29

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:05:17', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '650c997e-05b2-41ef-bede-c2f384bc6e00'	System	21 Aug 2020 00:05:29
User entered '98.3'	System	21 Aug 2020 00:05:29

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:05:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '650c997e-05b2-41ef-bede-c2f384bc6e00'	System	21 Aug 2020 00:05:29
User entered 'No (N)'	System	21 Aug 2020 00:05:29

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:05:27', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '650c997e-05b2-41ef-bede-c2f384bc6e00'	System	21 Aug 2020 00:05:29
User entered '20 Aug 2020 19:05'	System	21 Aug 2020 00:05:29

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 3'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:20:57', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '1cbb03cf-20a2-4bc8-9fd8-912d14c4f993'	System	22 Aug 2020 01:21:17
User entered 'Yes (Y)'	System	22 Aug 2020 01:21:17

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:02', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '1cbb03cf-20a2-4bc8-9fd8-912d14c4f993'	System	22 Aug 2020 01:21:17
User entered '98.2'	System	22 Aug 2020 01:21:17

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:06', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '1cbb03cf-20a2-4bc8-9fd8-912d14c4f993'	System	22 Aug 2020 01:21:17
User entered 'No (N)'	System	22 Aug 2020 01:21:17

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:09', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '1cbb03cf-20a2-4bc8-9fd8-912d14c4f993'	System	22 Aug 2020 01:21:17
User entered '21 Aug 2020 20:21'	System	22 Aug 2020 01:21:17

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 4'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:14:17', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b238de12-97af-4695-aa95-e24969ee776f'	System	23 Aug 2020 00:14:38
User entered 'Yes (Y)'	System	23 Aug 2020 00:14:38

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:14:27', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b238de12-97af-4695-aa95-e24969ee776f' User entered '98.7'	System	23 Aug 2020 00:14:38
	System	23 Aug 2020 00:14:38

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:14:31', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b238de12-97af-4695-aa95-e24969ee776f'	System	23 Aug 2020 00:14:38
User entered 'No (N)'	System	23 Aug 2020 00:14:38

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:14:34', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b238de12-97af-4695-aa95-e24969ee776f'	System	23 Aug 2020 00:14:38
User entered '22 Aug 2020 19:14'	System	23 Aug 2020 00:14:38

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 5'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:23:57', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a36635c1-3480-41a6-8842-fc4e8d32318a'	System	24 Aug 2020 00:24:13
User entered 'Yes (Y)'	System	24 Aug 2020 00:24:13

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:24:01', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a36635c1-3480-41a6-8842-fc4e8d32318a'	System	24 Aug 2020 00:24:13
User entered '98.0'	System	24 Aug 2020 00:24:13

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:24:04', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a36635c1-3480-41a6-8842-fc4e8d32318a'	System	24 Aug 2020 00:24:13
User entered 'No (N)'	System	24 Aug 2020 00:24:13

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:24:10', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a36635c1-3480-41a6-8842-fc4e8d32318a'	System	24 Aug 2020 00:24:13
User entered '23 Aug 2020 19:24'	System	24 Aug 2020 00:24:13

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 6'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:40:49', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '090f3568-a147-4f3f-8dcb-83597f0677c3'	System	25 Aug 2020 00:41:08
User entered 'Yes (Y)'	System	25 Aug 2020 00:41:08

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:40:54', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '090f3568-a147-4f3f-8dcb-83597f0677c3'	System	25 Aug 2020 00:41:08
User entered '97.6'	System	25 Aug 2020 00:41:08

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '090f3568-a147-4f3f-8dcb-83597f0677c3'	System	25 Aug 2020 00:41:08
User entered 'No (N)'	System	25 Aug 2020 00:41:08

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:05', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '090f3568-a147-4f3f-8dcb-83597f0677c3'	System	25 Aug 2020 00:41:08
User entered '24 Aug 2020 19:41'	System	25 Aug 2020 00:41:08

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 7'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:30:48', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '228cd512-4285-4c7a-adf6-58a374aa9463'	System	25 Aug 2020 22:31:05
User entered 'Yes (Y)'	System	25 Aug 2020 22:31:05

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:30:55', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '228cd512-4285-4c7a-adf6-58a374aa9463'	System	25 Aug 2020 22:31:05
User entered '98.0'	System	25 Aug 2020 22:31:05

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:30:57', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '228cd512-4285-4c7a-adf6-58a374aa9463'	System	25 Aug 2020 22:31:05
User entered 'No (N)'	System	25 Aug 2020 22:31:05

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '228cd512-4285-4c7a-adf6-58a374aa9463'	System	25 Aug 2020 22:31:05
User entered '25 Aug 2020 17:31'	System	25 Aug 2020 22:31:05

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:08', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2f2c64e6-f25f-4c44-9ec3-9cf922a38522'	System	20 Aug 2020 00:41:27
User entered 'None (1)'	System	20 Aug 2020 00:41:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:12', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2f2c64e6-f25f-4c44-9ec3-9cf922a38522'	System	20 Aug 2020 00:41:27
User entered 'No (N)'	System	20 Aug 2020 00:41:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:15', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2f2c64e6-f25f-4c44-9ec3-9cf922a38522'	System	20 Aug 2020 00:41:27
User entered 'No (N)'	System	20 Aug 2020 00:41:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2f2c64e6-f25f-4c44-9ec3-9cf922a38522'	System	20 Aug 2020 00:41:27
User entered 'None (1)'	System	20 Aug 2020 00:41:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:25', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2f2c64e6-f25f-4c44-9ec3-9cf922a38522'	System	20 Aug 2020 00:41:27
User entered '19 Aug 2020 19:41'	System	20 Aug 2020 00:41:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Aug 2020 19:21'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Aug 2020 21:51'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:42:17', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2055c5d3-03d4-48f9-aeed-0730f88ba94d'	System	20 Aug 2020 13:42:41
User entered 'None (1)'	System	20 Aug 2020 13:42:41

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:42:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2055c5d3-03d4-48f9-aeed-0730f88ba94d'	System	20 Aug 2020 13:42:41
User entered 'No (N)'	System	20 Aug 2020 13:42:41

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:42:27', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2055c5d3-03d4-48f9-aeed-0730f88ba94d'	System	20 Aug 2020 13:42:41
User entered 'No (N)'	System	20 Aug 2020 13:42:41

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:42:31', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2055c5d3-03d4-48f9-aeed-0730f88ba94d'	System	20 Aug 2020 13:42:41
User entered 'None (1)'	System	20 Aug 2020 13:42:41

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:42:37', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2055c5d3-03d4-48f9-aeed-0730f88ba94d'	System	20 Aug 2020 13:42:41
User entered '20 Aug 2020 08:42'	System	20 Aug 2020 13:42:41

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Aug 2020 22:46'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '20 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 2'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:05:32', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'da5cef68-f65f-454f-ab1e-31c0686add25'	System	21 Aug 2020 00:06:03
User entered 'None (1)'	System	21 Aug 2020 00:06:03

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:05:36', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'da5cef68-f65f-454f-ab1e-31c0686add25'	System	21 Aug 2020 00:06:03
User entered 'No (N)'	System	21 Aug 2020 00:06:03

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:05:39', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'da5cef68-f65f-454f-ab1e-31c0686add25'	System	21 Aug 2020 00:06:03
User entered 'No (N)'	System	21 Aug 2020 00:06:03

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:05:49', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'da5cef68-f65f-454f-ab1e-31c0686add25'	System	21 Aug 2020 00:06:03
User entered 'None (1)'	System	21 Aug 2020 00:06:03

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:05:57', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'da5cef68-f65f-454f-ab1e-31c0686add25'	System	21 Aug 2020 00:06:03
User entered '20 Aug 2020 19:05'	System	21 Aug 2020 00:06:03

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 3'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:13', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2202c03c-4751-421d-8798-add9925a1a06'	System	22 Aug 2020 01:21:34
User entered 'None (1)'	System	22 Aug 2020 01:21:34

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:16', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2202c03c-4751-421d-8798-add9925a1a06'	System	22 Aug 2020 01:21:34
User entered 'No (N)'	System	22 Aug 2020 01:21:34

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2202c03c-4751-421d-8798-add9925a1a06'	System	22 Aug 2020 01:21:34
User entered 'No (N)'	System	22 Aug 2020 01:21:34

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:23', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2202c03c-4751-421d-8798-add9925a1a06'	System	22 Aug 2020 01:21:34
User entered 'None (1)'	System	22 Aug 2020 01:21:34

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:26', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2202c03c-4751-421d-8798-add9925a1a06'	System	22 Aug 2020 01:21:34
User entered '21 Aug 2020 20:21'	System	22 Aug 2020 01:21:34

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 4'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:14:39', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '970071eb-9f7e-48a2-b2bd-ecc791313fb1'	System	23 Aug 2020 00:15:05
User entered 'None (1)'	System	23 Aug 2020 00:15:05

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:14:42', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '970071eb-9f7e-48a2-b2bd-ecc791313fb1'	System	23 Aug 2020 00:15:05
User entered 'No (N)'	System	23 Aug 2020 00:15:05

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:14:44', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '970071eb-9f7e-48a2-b2bd-ecc791313fb1'	System	23 Aug 2020 00:15:05
User entered 'No (N)'	System	23 Aug 2020 00:15:05

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:14:47', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '970071eb-9f7e-48a2-b2bd-ecc791313fb1'	System	23 Aug 2020 00:15:05
User entered 'None (1)'	System	23 Aug 2020 00:15:05

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:14:49', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '970071eb-9f7e-48a2-b2bd-ecc791313fb1'	System	23 Aug 2020 00:15:05
User entered '22 Aug 2020 19:14'	System	23 Aug 2020 00:15:05

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 5'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:24:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9bd0c3bc-15c6-4f0b-b620-df5c941a3fc8'	System	24 Aug 2020 00:24:49
User entered 'None (1)'	System	24 Aug 2020 00:24:49

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:24:36', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9bd0c3bc-15c6-4f0b-b620-df5c941a3fc8'	System	24 Aug 2020 00:24:49
User entered 'No (N)'	System	24 Aug 2020 00:24:49

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:24:40', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9bd0c3bc-15c6-4f0b-b620-df5c941a3fc8'	System	24 Aug 2020 00:24:49
User entered 'No (N)'	System	24 Aug 2020 00:24:49

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:24:42', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9bd0c3bc-15c6-4f0b-b620-df5c941a3fc8'	System	24 Aug 2020 00:24:49
User entered 'None (1)'	System	24 Aug 2020 00:24:49

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:24:45', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9bd0c3bc-15c6-4f0b-b620-df5c941a3fc8'	System	24 Aug 2020 00:24:49
User entered '23 Aug 2020 19:24'	System	24 Aug 2020 00:24:49

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 6'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:10', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '3910669a-9c21-40ec-9041-d765a370b2f0'	System	25 Aug 2020 00:41:31
User entered 'None (1)'	System	25 Aug 2020 00:41:31

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:13', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '3910669a-9c21-40ec-9041-d765a370b2f0'	System	25 Aug 2020 00:41:31
User entered 'No (N)'	System	25 Aug 2020 00:41:31

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:16', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '3910669a-9c21-40ec-9041-d765a370b2f0'	System	25 Aug 2020 00:41:31
User entered 'No (N)'	System	25 Aug 2020 00:41:31

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:20', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '3910669a-9c21-40ec-9041-d765a370b2f0'	System	25 Aug 2020 00:41:31
User entered 'None (1)'	System	25 Aug 2020 00:41:31

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:23', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '3910669a-9c21-40ec-9041-d765a370b2f0'	System	25 Aug 2020 00:41:31
User entered '24 Aug 2020 19:41'	System	25 Aug 2020 00:41:31

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 7'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:05', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0452b3df-83ee-4ae5-8de8-4fe3413abeea'	System	25 Aug 2020 22:31:21
User entered 'None (1)'	System	25 Aug 2020 22:31:21

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:07', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0452b3df-83ee-4ae5-8de8-4fe3413abeea'	System	25 Aug 2020 22:31:21
User entered 'No (N)'	System	25 Aug 2020 22:31:21

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:11', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0452b3df-83ee-4ae5-8de8-4fe3413abeea'	System	25 Aug 2020 22:31:21
User entered 'No (N)'	System	25 Aug 2020 22:31:21

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:14', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0452b3df-83ee-4ae5-8de8-4fe3413abeea'	System	25 Aug 2020 22:31:21
User entered 'None (1)'	System	25 Aug 2020 22:31:21

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:17', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0452b3df-83ee-4ae5-8de8-4fe3413abeea'	System	25 Aug 2020 22:31:21
User entered '25 Aug 2020 17:31'	System	25 Aug 2020 22:31:21

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:35', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '655ba9e0-f55a-4f3d-8a60-282251235200'	System	20 Aug 2020 00:42:01
User entered 'None (0)'	System	20 Aug 2020 00:42:01

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:38', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '655ba9e0-f55a-4f3d-8a60-282251235200'	System	20 Aug 2020 00:42:01
User entered 'None (0)'	System	20 Aug 2020 00:42:01

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:40', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '655ba9e0-f55a-4f3d-8a60-282251235200'	System	20 Aug 2020 00:42:01
User entered 'None (0)'	System	20 Aug 2020 00:42:01

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:44', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '655ba9e0-f55a-4f3d-8a60-282251235200'	System	20 Aug 2020 00:42:01
User entered 'None (0)'	System	20 Aug 2020 00:42:01

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:46', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '655ba9e0-f55a-4f3d-8a60-282251235200'	System	20 Aug 2020 00:42:01
User entered 'None (0)'	System	20 Aug 2020 00:42:01

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:47', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '655ba9e0-f55a-4f3d-8a60-282251235200'	System	20 Aug 2020 00:42:01
User entered 'None (0)'	System	20 Aug 2020 00:42:01

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:51', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '655ba9e0-f55a-4f3d-8a60-282251235200'	System	20 Aug 2020 00:42:01
User entered 'No (N)'	System	20 Aug 2020 00:42:01

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-19T19:41:53', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '655ba9e0-f55a-4f3d-8a60-282251235200'	System	20 Aug 2020 00:42:01
User entered '19 Aug 2020 19:41'	System	20 Aug 2020 00:42:01

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Aug 2020 19:21'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Aug 2020 21:51'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:42:46', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ebe1a396-2816-4f1c-8d30-605188b5842b'	System	20 Aug 2020 13:43:32
User entered 'None (0)'	System	20 Aug 2020 13:43:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:42:51', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ebe1a396-2816-4f1c-8d30-605188b5842b'	System	20 Aug 2020 13:43:32
User entered 'None (0)'	System	20 Aug 2020 13:43:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:42:56', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ebe1a396-2816-4f1c-8d30-605188b5842b' User entered 'None (0)'	System	20 Aug 2020 13:43:32
	System	20 Aug 2020 13:43:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:43:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ebe1a396-2816-4f1c-8d30-605188b5842b' User entered 'None (0)'	System	20 Aug 2020 13:43:32
	System	20 Aug 2020 13:43:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:43:02', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ebe1a396-2816-4f1c-8d30-605188b5842b' User entered 'None (0)'	System	20 Aug 2020 13:43:32
	System	20 Aug 2020 13:43:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:43:04', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ebe1a396-2816-4f1c-8d30-605188b5842b'	System	20 Aug 2020 13:43:32
User entered 'None (0)'	System	20 Aug 2020 13:43:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:43:08', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ebe1a396-2816-4f1c-8d30-605188b5842b'	System	20 Aug 2020 13:43:32
User entered 'No (N)'	System	20 Aug 2020 13:43:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T08:43:29', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ebe1a396-2816-4f1c-8d30-605188b5842b' User entered '20 Aug 2020 08:43'	System	20 Aug 2020 13:43:32
	System	20 Aug 2020 13:43:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Aug 2020 22:46'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '20 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 2'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:06:02', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '383a747a-30f7-4592-a951-45a37f8cf1e7'	System	21 Aug 2020 00:06:52
User entered 'None (0)'	System	21 Aug 2020 00:06:52

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:06:09', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '383a747a-30f7-4592-a951-45a37f8cf1e7'	System	21 Aug 2020 00:06:52
User entered 'None (0)'	System	21 Aug 2020 00:06:52

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:06:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '383a747a-30f7-4592-a951-45a37f8cf1e7'	System	21 Aug 2020 00:06:52
User entered 'None (0)'	System	21 Aug 2020 00:06:52

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:06:23', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '383a747a-30f7-4592-a951-45a37f8cf1e7'	System	21 Aug 2020 00:06:52
User entered 'None (0)'	System	21 Aug 2020 00:06:52

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:06:27', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '383a747a-30f7-4592-a951-45a37f8cf1e7'	System	21 Aug 2020 00:06:52
User entered 'None (0)'	System	21 Aug 2020 00:06:52

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:06:35', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '383a747a-30f7-4592-a951-45a37f8cf1e7'	System	21 Aug 2020 00:06:52
User entered 'None (0)'	System	21 Aug 2020 00:06:52

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:06:42', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '383a747a-30f7-4592-a951-45a37f8cf1e7'	System	21 Aug 2020 00:06:52
User entered 'No (N)'	System	21 Aug 2020 00:06:52

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-20T19:06:49', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '383a747a-30f7-4592-a951-45a37f8cf1e7'	System	21 Aug 2020 00:06:52
User entered '20 Aug 2020 19:06'	System	21 Aug 2020 00:06:52

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '20 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 3'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:33', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '4d11f004-21cc-43b2-a31b-5364c7d8e5ac'	System	22 Aug 2020 01:21:56
User entered 'None (0)'	System	22 Aug 2020 01:21:56

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:35', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '4d11f004-21cc-43b2-a31b-5364c7d8e5ac'	System	22 Aug 2020 01:21:56
User entered 'None (0)'	System	22 Aug 2020 01:21:56

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:39', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '4d11f004-21cc-43b2-a31b-5364c7d8e5ac'	System	22 Aug 2020 01:21:56
User entered 'None (0)'	System	22 Aug 2020 01:21:56

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:43', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '4d11f004-21cc-43b2-a31b-5364c7d8e5ac'	System	22 Aug 2020 01:21:56
User entered 'None (0)'	System	22 Aug 2020 01:21:56

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:45', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '4d11f004-21cc-43b2-a31b-5364c7d8e5ac'	System	22 Aug 2020 01:21:56
User entered 'None (0)'	System	22 Aug 2020 01:21:56

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:47', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '4d11f004-21cc-43b2-a31b-5364c7d8e5ac'	System	22 Aug 2020 01:21:56
User entered 'None (0)'	System	22 Aug 2020 01:21:56

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:50', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '4d11f004-21cc-43b2-a31b-5364c7d8e5ac'	System	22 Aug 2020 01:21:56
User entered 'No (N)'	System	22 Aug 2020 01:21:56

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-21T20:21:53', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '4d11f004-21cc-43b2-a31b-5364c7d8e5ac'	System	22 Aug 2020 01:21:56
User entered '21 Aug 2020 20:21'	System	22 Aug 2020 01:21:56

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 4'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:14:55', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0b37911d-a61e-435f-b82e-9a24a5e9a1b3'	System	23 Aug 2020 00:15:23
User entered 'None (0)'	System	23 Aug 2020 00:15:23

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:15:02', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0b37911d-a61e-435f-b82e-9a24a5e9a1b3'	System	23 Aug 2020 00:15:23
User entered 'None (0)'	System	23 Aug 2020 00:15:23

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:15:04', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0b37911d-a61e-435f-b82e-9a24a5e9a1b3'	System	23 Aug 2020 00:15:23
User entered 'None (0)'	System	23 Aug 2020 00:15:23

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:15:07', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0b37911d-a61e-435f-b82e-9a24a5e9a1b3'	System	23 Aug 2020 00:15:23
User entered 'None (0)'	System	23 Aug 2020 00:15:23

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:15:10', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0b37911d-a61e-435f-b82e-9a24a5e9a1b3'	System	23 Aug 2020 00:15:23
User entered 'None (0)'	System	23 Aug 2020 00:15:23

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:15:12', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0b37911d-a61e-435f-b82e-9a24a5e9a1b3'	System	23 Aug 2020 00:15:23
User entered 'None (0)'	System	23 Aug 2020 00:15:23

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:15:16', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0b37911d-a61e-435f-b82e-9a24a5e9a1b3'	System	23 Aug 2020 00:15:23
User entered 'No (N)'	System	23 Aug 2020 00:15:23

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-22T19:15:18', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '0b37911d-a61e-435f-b82e-9a24a5e9a1b3'	System	23 Aug 2020 00:15:23
User entered '22 Aug 2020 19:15'	System	23 Aug 2020 00:15:23

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 5'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:24:54', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '01094649-b6ee-4312-b93e-8e4b6c43a3b3'	System	24 Aug 2020 00:25:25
User entered 'None (0)'	System	24 Aug 2020 00:25:25

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:24:57', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '01094649-b6ee-4312-b93e-8e4b6c43a3b3'	System	24 Aug 2020 00:25:25
User entered 'None (0)'	System	24 Aug 2020 00:25:25

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:25:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '01094649-b6ee-4312-b93e-8e4b6c43a3b3'	System	24 Aug 2020 00:25:25
User entered 'None (0)'	System	24 Aug 2020 00:25:25

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:25:03', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '01094649-b6ee-4312-b93e-8e4b6c43a3b3'	System	24 Aug 2020 00:25:25
User entered 'None (0)'	System	24 Aug 2020 00:25:25

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:25:06', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '01094649-b6ee-4312-b93e-8e4b6c43a3b3'	System	24 Aug 2020 00:25:25
User entered 'None (0)'	System	24 Aug 2020 00:25:25

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:25:09', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '01094649-b6ee-4312-b93e-8e4b6c43a3b3'	System	24 Aug 2020 00:25:25
User entered 'None (0)'	System	24 Aug 2020 00:25:25

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:25:18', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '01094649-b6ee-4312-b93e-8e4b6c43a3b3'	System	24 Aug 2020 00:25:25
User entered 'No (N)'	System	24 Aug 2020 00:25:25

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-23T19:25:20', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '01094649-b6ee-4312-b93e-8e4b6c43a3b3'	System	24 Aug 2020 00:25:25
User entered '23 Aug 2020 19:25'	System	24 Aug 2020 00:25:25

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 6'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:28', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9448d4a9-08fa-486a-ab8a-07589dc68106'	System	25 Aug 2020 00:42:32
User entered 'None (0)'	System	25 Aug 2020 00:42:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:30', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9448d4a9-08fa-486a-ab8a-07589dc68106'	System	25 Aug 2020 00:42:32
User entered 'None (0)'	System	25 Aug 2020 00:42:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:34', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9448d4a9-08fa-486a-ab8a-07589dc68106'	System	25 Aug 2020 00:42:32
User entered 'None (0)'	System	25 Aug 2020 00:42:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:36', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9448d4a9-08fa-486a-ab8a-07589dc68106'	System	25 Aug 2020 00:42:32
User entered 'None (0)'	System	25 Aug 2020 00:42:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:46', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9448d4a9-08fa-486a-ab8a-07589dc68106'	System	25 Aug 2020 00:42:32
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	25 Aug 2020 00:42:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:41:49', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9448d4a9-08fa-486a-ab8a-07589dc68106'	System	25 Aug 2020 00:42:32
User entered 'None (0)'	System	25 Aug 2020 00:42:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:42:01', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9448d4a9-08fa-486a-ab8a-07589dc68106'	System	25 Aug 2020 00:42:32
User entered 'No (N)'	System	25 Aug 2020 00:42:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-24T19:42:27', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '9448d4a9-08fa-486a-ab8a-07589dc68106'	System	25 Aug 2020 00:42:32
User entered '24 Aug 2020 19:42'	System	25 Aug 2020 00:42:32

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 7'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:20', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'd849de1f-6567-4f05-bc77-884ef43ba07f'	System	25 Aug 2020 22:31:43
User entered 'None (0)'	System	25 Aug 2020 22:31:43

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:22', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'd849de1f-6567-4f05-bc77-884ef43ba07f'	System	25 Aug 2020 22:31:43
User entered 'None (0)'	System	25 Aug 2020 22:31:43

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:24', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'd849de1f-6567-4f05-bc77-884ef43ba07f'	System	25 Aug 2020 22:31:43
User entered 'None (0)'	System	25 Aug 2020 22:31:43

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:26', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'd849de1f-6567-4f05-bc77-884ef43ba07f'	System	25 Aug 2020 22:31:43
User entered 'None (0)'	System	25 Aug 2020 22:31:43

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:28', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'd849de1f-6567-4f05-bc77-884ef43ba07f'	System	25 Aug 2020 22:31:43
User entered 'None (0)'	System	25 Aug 2020 22:31:43

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:31', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'd849de1f-6567-4f05-bc77-884ef43ba07f'	System	25 Aug 2020 22:31:43
User entered 'None (0)'	System	25 Aug 2020 22:31:43

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:34', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'd849de1f-6567-4f05-bc77-884ef43ba07f'	System	25 Aug 2020 22:31:43
User entered 'No (N)'	System	25 Aug 2020 22:31:43

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-08-25T17:31:37', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'd849de1f-6567-4f05-bc77-884ef43ba07f'	System	25 Aug 2020 22:31:43
User entered '25 Aug 2020 17:31'	System	25 Aug 2020 22:31:43

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 00:09:27

US3272195

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:07
User entered 'Yes (Y)'		02 Sep 2020 17:01:14

US3272195

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:07
User entered '26 Aug 2020'		02 Sep 2020 17:01:14

US3272195

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:07
User entered 'Contact Made (CONTACT MADE)'		02 Sep 2020 17:01:14

US3272195

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:07
User entered empty.		02 Sep 2020 17:01:14

US3272195

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:40:15
User entered 'Yes (Y)'		02 Sep 2020 17:01:19

US3272195

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:21
User entered 'I'	System	02 Sep 2020 17:01:19

US3272195

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:47:07
User entered 'Yes (Y)'		02 Sep 2020 17:01:31

US3272195

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:47:07
User entered '02 Sep 2020'		02 Sep 2020 17:01:31

US3272195

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:47:07
User entered 'Contact Made (CONTACT MADE)'		02 Sep 2020 17:01:31

US3272195

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:47:07
User entered empty.		02 Sep 2020 17:01:31

US3272195

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 16:47:13
User entered 'Yes (Y)'		02 Sep 2020 17:01:34

US3272195

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:02:17
User entered '1'	System	02 Sep 2020 17:01:34

US3272195

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:30:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:02
User entered 'Yes (Y)'		16 Sep 2020 00:03:09

US3272195

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:30:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:02
User entered '9 Sep 2020'		16 Sep 2020 00:03:09

US3272195

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:30:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:02
User entered 'Contact Made (CONTACT MADE)'		16 Sep 2020 00:03:09

US3272195

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:30:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:02
User entered empty.		16 Sep 2020 00:03:09

US3272195

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:30:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:47:57
User entered 'Yes (Y)'		16 Sep 2020 00:03:16

US3272195

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:30:00
User entered 'I'	System	16 Sep 2020 00:03:16

US3272195

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:19
User entered 'Yes (Y)'		18 Sep 2020 15:14:43

US3272195

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:19
User entered '17 Sep 2020'		18 Sep 2020 15:14:43

US3272195

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:19
User entered 'Clinic (Clinic)'		18 Sep 2020 15:14:43

US3272195

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered 'VISIT2'	System	18 Sep 2020 15:14:43

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User accepted default value 'Pre-Dose (PREDOSE)'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered 'Yes (Y)'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '17 Sep 2020'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '16:05'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered '17 Sep 2020 16:05'	System	18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '36.8' C		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered 'Oral (Oral)'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered empty.		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '94'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered 'bpm'	System	18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '16'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered 'breaths/min'	System	18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '122'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered 'mmHg'	System	18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '84'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered 'mmHg'	System	18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User accepted default value 'Post-Dose (POSTDOSE)'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered 'Yes (Y)'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '17 Sep 2020'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '17:30'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered '17 Sep 2020 17:30'	System	18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '36.8' C		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered 'Oral (Oral)'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered empty.		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '96'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered 'bpm'	System	18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '16'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered 'breaths/min'	System	18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '118'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered 'mmHg'	System	18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:23
User entered '78'		18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered 'mmHg'	System	18 Sep 2020 15:16:46

US3272195

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:27
User entered 'Yes (Y)'		18 Sep 2020 15:16:55

US3272195

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:27
User entered '17 Sep 2020'		18 Sep 2020 15:16:55

US3272195

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:31
User entered 'Yes (Y)'		18 Sep 2020 15:17:02

US3272195

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:31
User entered '17 Sep 2020'		18 Sep 2020 15:17:02

US3272195

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:31
User entered 'Urine (URINE)'		18 Sep 2020 15:17:02

US3272195

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:31
User entered 'Negative (NEGATIVE)'		18 Sep 2020 15:17:02

US3272195

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:31
User entered 'No (N)'		18 Sep 2020 15:17:02

US3272195

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:31
User entered empty.		18 Sep 2020 15:17:02

US3272195

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:48:31
User entered empty.		18 Sep 2020 15:17:02

US3272195

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered empty.	System	18 Sep 2020 15:17:02

US3272195

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:47:34
User entered 'Yes (Y)'	Kayla Flege (b) (4)	17 Sep 2020 22:00:10
	(b) (4)	

US3272195

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:47:34
User entered empty.	Kayla Flege (b) (4)	17 Sep 2020 22:00:10
	(b) (4)	

US3272195

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

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)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:47:34
User entered empty.	Kayla Flege (b) (4) (b) (4)	17 Sep 2020 22:00:10

US3272195

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 22:00:10

US3272195

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:47:34
User entered '17 Sep 2020'	Kayla Flege (b) (4)	17 Sep 2020 22:00:10
	(b) (4)	

US3272195

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:47:34
User entered '16:54'	Kayla Flege (b) (4) (b) (4)	17 Sep 2020 22:00:10

US3272195

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered '17 Sep 2020 16:54'	System	17 Sep 2020 22:00:10

US3272195

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:47:34
User entered 'Left Arm (LEFT ARM)'	Kayla Flege (b) (4) (b) (4)	17 Sep 2020 22:00:10

US3272195

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
DataPoint Verified.		22 Apr 2021 14:47:34
User entered 'ONCE'	System	17 Sep 2020 22:00:10

US3272195

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 22:00:10

US3272195

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:04
User entered 'Yes (Y)'		18 Sep 2020 15:17:16

US3272195

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:04
User entered '17 Sep 2020'		18 Sep 2020 15:17:16

US3272195

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:04
User entered '16:13'		18 Sep 2020 15:17:16

US3272195

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered '17 Sep 2020 16:13'	System	18 Sep 2020 15:17:16

US3272195

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:23:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:17
User entered '17 Sep 2020'		18 Sep 2020 15:17:25

US3272195

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		18 Sep 2020 15:17:25

US3272195

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:17
User entered 'Yes (Y)'		18 Sep 2020 15:17:25

US3272195

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:17
User entered '16:10'		18 Sep 2020 15:17:25

US3272195

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered '17 Sep 2020 16:10'	System	18 Sep 2020 15:17:25

US3272195

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		18 Sep 2020 15:17:25

US3272195

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:17
User entered 'No (N)'		18 Sep 2020 15:17:25

US3272195

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:17
User entered empty.		18 Sep 2020 15:17:25

US3272195

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered empty.	System	18 Sep 2020 15:17:25

US3272195

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:26
User entered 'Yes (Y)'		18 Sep 2020 15:17:57

US3272195

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:10:46
User entered 'I'	System	18 Sep 2020 15:17:57

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:25:04', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b596f823-7e51-45b2-b67c-33f997ff1f2b'	System	17 Sep 2020 22:25:28
User entered 'Yes (Y)'	System	17 Sep 2020 22:25:28

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:25:09', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b596f823-7e51-45b2-b67c-33f997ff1f2b'	System	17 Sep 2020 22:25:28
User entered '98.3'	System	17 Sep 2020 22:25:28

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:25:13', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b596f823-7e51-45b2-b67c-33f997ff1f2b'	System	17 Sep 2020 22:25:28
User entered 'No (N)'	System	17 Sep 2020 22:25:28

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:25:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b596f823-7e51-45b2-b67c-33f997ff1f2b'	System	17 Sep 2020 22:25:28
User entered '17 Sep 2020 17:25'	System	17 Sep 2020 22:25:28

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '17 Sep 2020 17:14'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '17 Sep 2020 19:44'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:40:15', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '17f01640-8b9e-4af4-b99a-30874778e85c'	System	18 Sep 2020 01:40:34
User entered 'Yes (Y)'	System	18 Sep 2020 01:40:34

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:40:20', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '17f01640-8b9e-4af4-b99a-30874778e85c'	System	18 Sep 2020 01:40:34
User entered '98.3'	System	18 Sep 2020 01:40:34

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:40:23', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '17f01640-8b9e-4af4-b99a-30874778e85c'	System	18 Sep 2020 01:40:34
User entered 'No (N)'	System	18 Sep 2020 01:40:34

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:40:26', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '17f01640-8b9e-4af4-b99a-30874778e85c'	System	18 Sep 2020 01:40:34
User entered '17 Sep 2020 20:40'	System	18 Sep 2020 01:40:34

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '17 Sep 2020 20:39'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 2'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:10:38', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'd6cd51eb-f6b0-4a31-8a30-c065a1b1c2c0'	System	19 Sep 2020 01:11:00
User entered 'Yes (Y)'	System	19 Sep 2020 01:11:00

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:10:42', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'd6cd51eb-f6b0-4a31-8a30-c065a1b1c2c0'	System	19 Sep 2020 01:11:00
User entered '98.6'	System	19 Sep 2020 01:11:00

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:10:49', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'd6cd51eb-f6b0-4a31-8a30-c065a1b1c2c0'	System	19 Sep 2020 01:11:00
User entered 'No (N)'	System	19 Sep 2020 01:11:00

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:10:52', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'd6cd51eb-f6b0-4a31-8a30-c065a1b1c2c0'	System	19 Sep 2020 01:11:00
User entered '18 Sep 2020 20:10'	System	19 Sep 2020 01:11:00

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 3'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:23', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'f87ecca3-e882-44e9-9972-c0fb8da38688'	System	20 Sep 2020 05:19:34
User entered 'No (N)'	System	20 Sep 2020 05:19:34

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:26', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'f87ecca3-e882-44e9-9972-c0fb8da38688'	System	20 Sep 2020 05:19:34
User entered 'No (N)'	System	20 Sep 2020 05:19:34

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:29', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'f87ecca3-e882-44e9-9972-c0fb8da38688'	System	20 Sep 2020 05:19:34
User entered '20 Sep 2020 00:19'	System	20 Sep 2020 05:19:34

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 4'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:16:32', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a3974252-2bb9-4fba-8ebb-7f47276d059e'	System	21 Sep 2020 03:16:53
User entered 'Yes (Y)'	System	21 Sep 2020 03:16:53

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:16:35', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a3974252-2bb9-4fba-8ebb-7f47276d059e'	System	21 Sep 2020 03:16:53
User entered '98.9'	System	21 Sep 2020 03:16:53

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:16:44', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a3974252-2bb9-4fba-8ebb-7f47276d059e'	System	21 Sep 2020 03:16:53
User entered 'No (N)'	System	21 Sep 2020 03:16:53

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:16:47', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a3974252-2bb9-4fba-8ebb-7f47276d059e'	System	21 Sep 2020 03:16:53
User entered '20 Sep 2020 22:16'	System	21 Sep 2020 03:16:53

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 5'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:15:36', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '24ecb045-701e-45be-9819-f5b4e6e731d2'	System	22 Sep 2020 01:16:00
User entered 'Yes (Y)'	System	22 Sep 2020 01:16:00

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:15:45', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '24ecb045-701e-45be-9819-f5b4e6e731d2'	System	22 Sep 2020 01:16:00
User entered '97.4'	System	22 Sep 2020 01:16:00

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:15:52', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '24ecb045-701e-45be-9819-f5b4e6e731d2'	System	22 Sep 2020 01:16:00
User entered 'No (N)'	System	22 Sep 2020 01:16:00

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:15:56', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '24ecb045-701e-45be-9819-f5b4e6e731d2'	System	22 Sep 2020 01:16:00
User entered '21 Sep 2020 20:15'	System	22 Sep 2020 01:16:00

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 6'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:25', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'dd816dc4-1d60-499b-804f-e38f84230b4f'	System	23 Sep 2020 00:32:39
User entered 'Yes (Y)'	System	23 Sep 2020 00:32:39

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:29', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'dd816dc4-1d60-499b-804f-e38f84230b4f'	System	23 Sep 2020 00:32:39
User entered '98.4'	System	23 Sep 2020 00:32:39

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:32', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'dd816dc4-1d60-499b-804f-e38f84230b4f'	System	23 Sep 2020 00:32:39
User entered 'No (N)'	System	23 Sep 2020 00:32:39

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:35', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'dd816dc4-1d60-499b-804f-e38f84230b4f'	System	23 Sep 2020 00:32:39
User entered '22 Sep 2020 19:32'	System	23 Sep 2020 00:32:39

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 7'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:33:45', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'f808ebce-dce7-4ce1-b49f-a653d2d008eb'	System	24 Sep 2020 11:34:04
User entered 'Yes (Y)'	System	24 Sep 2020 11:34:04

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:33:53', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'f808ebce-dce7-4ce1-b49f-a653d2d008eb'	System	24 Sep 2020 11:34:04
User entered '97.4'	System	24 Sep 2020 11:34:04

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:33:57', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'f808ebce-dce7-4ce1-b49f-a653d2d008eb'	System	24 Sep 2020 11:34:04
User entered 'No (N)'	System	24 Sep 2020 11:34:04

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:33:59', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'f808ebce-dce7-4ce1-b49f-a653d2d008eb'	System	24 Sep 2020 11:34:04
User entered '24 Sep 2020 06:33'	System	24 Sep 2020 11:34:04

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:25:43', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a0ebd0ff-17bf-4c2e-9ad2-6e64d7c0e044'	System	17 Sep 2020 22:26:00
User entered 'None (1)'	System	17 Sep 2020 22:26:00

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:25:48', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a0ebd0ff-17bf-4c2e-9ad2-6e64d7c0e044'	System	17 Sep 2020 22:26:00
User entered 'No (N)'	System	17 Sep 2020 22:26:00

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:25:50', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a0ebd0ff-17bf-4c2e-9ad2-6e64d7c0e044'	System	17 Sep 2020 22:26:00
User entered 'No (N)'	System	17 Sep 2020 22:26:00

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:25:53', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a0ebd0ff-17bf-4c2e-9ad2-6e64d7c0e044'	System	17 Sep 2020 22:26:00
User entered 'None (1)'	System	17 Sep 2020 22:26:00

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:25:56', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a0ebd0ff-17bf-4c2e-9ad2-6e64d7c0e044'	System	17 Sep 2020 22:26:00
User entered '17 Sep 2020 17:25'	System	17 Sep 2020 22:26:00

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '17 Sep 2020 17:14'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '17 Sep 2020 19:44'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:40:36', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '5a135af1-8c97-4858-861d-2f28bf827fcc'	System	18 Sep 2020 01:41:00
User entered 'None (1)'	System	18 Sep 2020 01:41:00

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:40:45', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '5a135af1-8c97-4858-861d-2f28bf827fcc'	System	18 Sep 2020 01:41:00
User entered 'No (N)'	System	18 Sep 2020 01:41:00

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:40:47', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '5a135af1-8c97-4858-861d-2f28bf827fcc'	System	18 Sep 2020 01:41:00
User entered 'No (N)'	System	18 Sep 2020 01:41:00

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:40:50', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '5a135af1-8c97-4858-861d-2f28bf827fcc'	System	18 Sep 2020 01:41:00
User entered 'None (1)'	System	18 Sep 2020 01:41:00

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:40:53', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '5a135af1-8c97-4858-861d-2f28bf827fcc'	System	18 Sep 2020 01:41:00
User entered '17 Sep 2020 20:40'	System	18 Sep 2020 01:41:00

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '17 Sep 2020 20:39'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 2'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:10:57', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94d7cb0e-1794-499b-83b2-8d42d09cf308'	System	19 Sep 2020 01:11:24
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 01:11:24

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:11:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94d7cb0e-1794-499b-83b2-8d42d09cf308'	System	19 Sep 2020 01:11:24
User entered 'No (N)'	System	19 Sep 2020 01:11:24

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:11:10', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94d7cb0e-1794-499b-83b2-8d42d09cf308'	System	19 Sep 2020 01:11:24
User entered 'No (N)'	System	19 Sep 2020 01:11:24

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:11:16', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94d7cb0e-1794-499b-83b2-8d42d09cf308'	System	19 Sep 2020 01:11:24
User entered 'None (1)'	System	19 Sep 2020 01:11:24

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:11:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94d7cb0e-1794-499b-83b2-8d42d09cf308'	System	19 Sep 2020 01:11:24
User entered '18 Sep 2020 20:11'	System	19 Sep 2020 01:11:24

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 3'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:33', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b36aca93-594e-406b-b97e-4d1782313a62'	System	20 Sep 2020 05:19:51
User entered 'None (1)'	System	20 Sep 2020 05:19:51

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:37', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b36aca93-594e-406b-b97e-4d1782313a62'	System	20 Sep 2020 05:19:51
User entered 'No (N)'	System	20 Sep 2020 05:19:51

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:40', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b36aca93-594e-406b-b97e-4d1782313a62'	System	20 Sep 2020 05:19:51
User entered 'No (N)'	System	20 Sep 2020 05:19:51

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:45', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b36aca93-594e-406b-b97e-4d1782313a62'	System	20 Sep 2020 05:19:51
User entered 'None (1)'	System	20 Sep 2020 05:19:51

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:47', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b36aca93-594e-406b-b97e-4d1782313a62'	System	20 Sep 2020 05:19:51
User entered '20 Sep 2020 00:19'	System	20 Sep 2020 05:19:51

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 4'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:16:50', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '42d3097d-fe59-4aec-b610-ddede0f43ce6'	System	21 Sep 2020 03:17:05
User entered 'None (1)'	System	21 Sep 2020 03:17:05

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:16:52', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '42d3097d-fe59-4aec-b610-ddede0f43ce6'	System	21 Sep 2020 03:17:05
User entered 'No (N)'	System	21 Sep 2020 03:17:05

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:16:54', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '42d3097d-fe59-4aec-b610-ddede0f43ce6'	System	21 Sep 2020 03:17:05
User entered 'No (N)'	System	21 Sep 2020 03:17:05

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:16:55', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '42d3097d-fe59-4aec-b610-ddede0f43ce6'	System	21 Sep 2020 03:17:05
User entered 'None (1)'	System	21 Sep 2020 03:17:05

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:16:58', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '42d3097d-fe59-4aec-b610-ddede0f43ce6'	System	21 Sep 2020 03:17:05
User entered '20 Sep 2020 22:16'	System	21 Sep 2020 03:17:05

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 5'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:15:59', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '076789b2-a90d-476a-a72c-7fbfbdb4ba15'	System	22 Sep 2020 01:16:11
User entered 'None (1)'	System	22 Sep 2020 01:16:11

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:16:02', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '076789b2-a90d-476a-a72c-7fbfbdb4ba15'	System	22 Sep 2020 01:16:11
User entered 'No (N)'	System	22 Sep 2020 01:16:11

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:16:03', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '076789b2-a90d-476a-a72c-7fbfbdb4ba15'	System	22 Sep 2020 01:16:11
User entered 'No (N)'	System	22 Sep 2020 01:16:11

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:16:05', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '076789b2-a90d-476a-a72c-7fbfbdb4ba15'	System	22 Sep 2020 01:16:11
User entered 'None (1)'	System	22 Sep 2020 01:16:11

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:16:07', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '076789b2-a90d-476a-a72c-7fbfbdb4ba15'	System	22 Sep 2020 01:16:11
User entered '21 Sep 2020 20:16'	System	22 Sep 2020 01:16:11

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 6'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:38', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '842f7ede-15fb-4334-9fc3-4806e87a1114'	System	23 Sep 2020 00:32:51
User entered 'None (1)'	System	23 Sep 2020 00:32:51

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:40', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '842f7ede-15fb-4334-9fc3-4806e87a1114'	System	23 Sep 2020 00:32:51
User entered 'No (N)'	System	23 Sep 2020 00:32:51

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:42', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '842f7ede-15fb-4334-9fc3-4806e87a1114'	System	23 Sep 2020 00:32:51
User entered 'No (N)'	System	23 Sep 2020 00:32:51

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:45', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '842f7ede-15fb-4334-9fc3-4806e87a1114'	System	23 Sep 2020 00:32:51
User entered 'None (1)'	System	23 Sep 2020 00:32:51

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:47', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '842f7ede-15fb-4334-9fc3-4806e87a1114'	System	23 Sep 2020 00:32:51
User entered '22 Sep 2020 19:32'	System	23 Sep 2020 00:32:51

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 7'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:03', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ce790b02-981e-49e2-9422-6bf5150fcde7'	System	24 Sep 2020 11:34:22
User entered 'None (1)'	System	24 Sep 2020 11:34:22

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:08', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ce790b02-981e-49e2-9422-6bf5150fcde7'	System	24 Sep 2020 11:34:22
User entered 'No (N)'	System	24 Sep 2020 11:34:22

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:10', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ce790b02-981e-49e2-9422-6bf5150fcde7'	System	24 Sep 2020 11:34:22
User entered 'No (N)'	System	24 Sep 2020 11:34:22

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:11', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ce790b02-981e-49e2-9422-6bf5150fcde7'	System	24 Sep 2020 11:34:22
User entered 'None (1)'	System	24 Sep 2020 11:34:22

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:14', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ce790b02-981e-49e2-9422-6bf5150fcde7'	System	24 Sep 2020 11:34:22
User entered '24 Sep 2020 06:34'	System	24 Sep 2020 11:34:22

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:26:02', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94c794ef-0052-48a5-87fe-941451f76e9c'	System	17 Sep 2020 22:26:29
User entered 'None (0)'	System	17 Sep 2020 22:26:29

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:26:04', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94c794ef-0052-48a5-87fe-941451f76e9c'	System	17 Sep 2020 22:26:29
User entered 'None (0)'	System	17 Sep 2020 22:26:29

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:26:06', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94c794ef-0052-48a5-87fe-941451f76e9c'	System	17 Sep 2020 22:26:29
User entered 'None (0)'	System	17 Sep 2020 22:26:29

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:26:07', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94c794ef-0052-48a5-87fe-941451f76e9c'	System	17 Sep 2020 22:26:29
User entered 'None (0)'	System	17 Sep 2020 22:26:29

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:26:11', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94c794ef-0052-48a5-87fe-941451f76e9c'	System	17 Sep 2020 22:26:29
User entered 'None (0)'	System	17 Sep 2020 22:26:29

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:26:13', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94c794ef-0052-48a5-87fe-941451f76e9c'	System	17 Sep 2020 22:26:29
User entered 'None (0)'	System	17 Sep 2020 22:26:29

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:26:20', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94c794ef-0052-48a5-87fe-941451f76e9c'	System	17 Sep 2020 22:26:29
User entered 'No (N)'	System	17 Sep 2020 22:26:29

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T17:26:22', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '94c794ef-0052-48a5-87fe-941451f76e9c'	System	17 Sep 2020 22:26:29
User entered '17 Sep 2020 17:26'	System	17 Sep 2020 22:26:29

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '17 Sep 2020 17:14'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '17 Sep 2020 19:44'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:40:58', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '13b774d1-b278-4fcb-ac1e-e6707e036f93'	System	18 Sep 2020 01:41:20
User entered 'None (0)'	System	18 Sep 2020 01:41:20

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:41:01', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '13b774d1-b278-4fcb-ac1e-e6707e036f93'	System	18 Sep 2020 01:41:20
User entered 'None (0)'	System	18 Sep 2020 01:41:20

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:41:04', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '13b774d1-b278-4fcb-ac1e-e6707e036f93'	System	18 Sep 2020 01:41:20
User entered 'None (0)'	System	18 Sep 2020 01:41:20

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:41:05', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '13b774d1-b278-4fcb-ac1e-e6707e036f93'	System	18 Sep 2020 01:41:20
User entered 'None (0)'	System	18 Sep 2020 01:41:20

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:41:08', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '13b774d1-b278-4fcb-ac1e-e6707e036f93'	System	18 Sep 2020 01:41:20
User entered 'None (0)'	System	18 Sep 2020 01:41:20

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:41:09', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '13b774d1-b278-4fcb-ac1e-e6707e036f93'	System	18 Sep 2020 01:41:20
User entered 'None (0)'	System	18 Sep 2020 01:41:20

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:41:12', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '13b774d1-b278-4fcb-ac1e-e6707e036f93'	System	18 Sep 2020 01:41:20
User entered 'No (N)'	System	18 Sep 2020 01:41:20

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-17T20:41:14', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '13b774d1-b278-4fcb-ac1e-e6707e036f93'	System	18 Sep 2020 01:41:20
User entered '17 Sep 2020 20:41'	System	18 Sep 2020 01:41:20

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '17 Sep 2020 20:39'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 2'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:11:26', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '22d293e0-ce2a-425c-bb93-36cbc9d87ece'	System	19 Sep 2020 01:11:53
User entered 'None (0)'	System	19 Sep 2020 01:11:53

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:11:31', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '22d293e0-ce2a-425c-bb93-36cbc9d87ece'	System	19 Sep 2020 01:11:53
User entered 'None (0)'	System	19 Sep 2020 01:11:53

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:11:36', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '22d293e0-ce2a-425c-bb93-36cbc9d87ece'	System	19 Sep 2020 01:11:53
User entered 'None (0)'	System	19 Sep 2020 01:11:53

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:11:38', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '22d293e0-ce2a-425c-bb93-36cbc9d87ece'	System	19 Sep 2020 01:11:53
User entered 'None (0)'	System	19 Sep 2020 01:11:53

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:11:41', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '22d293e0-ce2a-425c-bb93-36cbc9d87ece'	System	19 Sep 2020 01:11:53
User entered 'None (0)'	System	19 Sep 2020 01:11:53

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:11:45', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '22d293e0-ce2a-425c-bb93-36cbc9d87ece'	System	19 Sep 2020 01:11:53
User entered 'None (0)'	System	19 Sep 2020 01:11:53

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:11:47', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '22d293e0-ce2a-425c-bb93-36cbc9d87ece'	System	19 Sep 2020 01:11:53
User entered 'No (N)'	System	19 Sep 2020 01:11:53

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-18T20:11:49', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '22d293e0-ce2a-425c-bb93-36cbc9d87ece'	System	19 Sep 2020 01:11:53
User entered '18 Sep 2020 20:11'	System	19 Sep 2020 01:11:53

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 3'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:51', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ca9b3e53-3a0e-491d-841c-9b8490484a0f'	System	20 Sep 2020 05:20:08
User entered 'None (0)'	System	20 Sep 2020 05:20:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:52', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ca9b3e53-3a0e-491d-841c-9b8490484a0f'	System	20 Sep 2020 05:20:08
User entered 'None (0)'	System	20 Sep 2020 05:20:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:54', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ca9b3e53-3a0e-491d-841c-9b8490484a0f'	System	20 Sep 2020 05:20:08
User entered 'None (0)'	System	20 Sep 2020 05:20:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:55', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ca9b3e53-3a0e-491d-841c-9b8490484a0f'	System	20 Sep 2020 05:20:08
User entered 'None (0)'	System	20 Sep 2020 05:20:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:19:58', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ca9b3e53-3a0e-491d-841c-9b8490484a0f'	System	20 Sep 2020 05:20:08
User entered 'None (0)'	System	20 Sep 2020 05:20:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:20:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ca9b3e53-3a0e-491d-841c-9b8490484a0f'	System	20 Sep 2020 05:20:08
User entered 'None (0)'	System	20 Sep 2020 05:20:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:20:02', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ca9b3e53-3a0e-491d-841c-9b8490484a0f'	System	20 Sep 2020 05:20:08
User entered 'No (N)'	System	20 Sep 2020 05:20:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T00:20:04', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'ca9b3e53-3a0e-491d-841c-9b8490484a0f'	System	20 Sep 2020 05:20:08
User entered '20 Sep 2020 00:20'	System	20 Sep 2020 05:20:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 4'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:17:01', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '49c219dd-0852-4ad2-9e03-da4a0cfbefbb'	System	21 Sep 2020 03:17:22
User entered 'None (0)'	System	21 Sep 2020 03:17:22

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:17:02', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '49c219dd-0852-4ad2-9e03-da4a0cfbefbb'	System	21 Sep 2020 03:17:22
User entered 'None (0)'	System	21 Sep 2020 03:17:22

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:17:04', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '49c219dd-0852-4ad2-9e03-da4a0cfbefbb'	System	21 Sep 2020 03:17:22
User entered 'None (0)'	System	21 Sep 2020 03:17:22

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:17:06', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '49c219dd-0852-4ad2-9e03-da4a0cfbefbb'	System	21 Sep 2020 03:17:22
User entered 'None (0)'	System	21 Sep 2020 03:17:22

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:17:08', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '49c219dd-0852-4ad2-9e03-da4a0cfbefbb'	System	21 Sep 2020 03:17:22
User entered 'None (0)'	System	21 Sep 2020 03:17:22

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:17:10', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '49c219dd-0852-4ad2-9e03-da4a0cfbefbb'	System	21 Sep 2020 03:17:22
User entered 'None (0)'	System	21 Sep 2020 03:17:22

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:17:14', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '49c219dd-0852-4ad2-9e03-da4a0cfbefbb'	System	21 Sep 2020 03:17:22
User entered 'No (N)'	System	21 Sep 2020 03:17:22

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-20T22:17:17', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '49c219dd-0852-4ad2-9e03-da4a0cfbefbb'	System	21 Sep 2020 03:17:22
User entered '20 Sep 2020 22:17'	System	21 Sep 2020 03:17:22

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 5'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:16:10', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2ea8bf31-da16-430e-853b-2a56438981f9'	System	22 Sep 2020 01:16:28
User entered 'None (0)'	System	22 Sep 2020 01:16:28

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:16:12', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2ea8bf31-da16-430e-853b-2a56438981f9'	System	22 Sep 2020 01:16:28
User entered 'None (0)'	System	22 Sep 2020 01:16:28

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:16:13', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2ea8bf31-da16-430e-853b-2a56438981f9'	System	22 Sep 2020 01:16:28
User entered 'None (0)'	System	22 Sep 2020 01:16:28

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:16:15', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2ea8bf31-da16-430e-853b-2a56438981f9'	System	22 Sep 2020 01:16:28
User entered 'None (0)'	System	22 Sep 2020 01:16:28

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:16:16', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2ea8bf31-da16-430e-853b-2a56438981f9'	System	22 Sep 2020 01:16:28
User entered 'None (0)'	System	22 Sep 2020 01:16:28

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:16:18', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2ea8bf31-da16-430e-853b-2a56438981f9'	System	22 Sep 2020 01:16:28
User entered 'None (0)'	System	22 Sep 2020 01:16:28

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:16:20', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2ea8bf31-da16-430e-853b-2a56438981f9'	System	22 Sep 2020 01:16:28
User entered 'No (N)'	System	22 Sep 2020 01:16:28

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-21T20:16:22', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2ea8bf31-da16-430e-853b-2a56438981f9'	System	22 Sep 2020 01:16:28
User entered '21 Sep 2020 20:16'	System	22 Sep 2020 01:16:28

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 6'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:50', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'bb38296f-bf5f-4586-b371-1ae5b39fe479'	System	23 Sep 2020 00:33:08
User entered 'None (0)'	System	23 Sep 2020 00:33:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:51', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'bb38296f-bf5f-4586-b371-1ae5b39fe479'	System	23 Sep 2020 00:33:08
User entered 'None (0)'	System	23 Sep 2020 00:33:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:53', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'bb38296f-bf5f-4586-b371-1ae5b39fe479'	System	23 Sep 2020 00:33:08
User entered 'None (0)'	System	23 Sep 2020 00:33:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:55', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'bb38296f-bf5f-4586-b371-1ae5b39fe479'	System	23 Sep 2020 00:33:08
User entered 'None (0)'	System	23 Sep 2020 00:33:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:56', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'bb38296f-bf5f-4586-b371-1ae5b39fe479'	System	23 Sep 2020 00:33:08
User entered 'None (0)'	System	23 Sep 2020 00:33:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:32:58', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'bb38296f-bf5f-4586-b371-1ae5b39fe479'	System	23 Sep 2020 00:33:08
User entered 'None (0)'	System	23 Sep 2020 00:33:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:33:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'bb38296f-bf5f-4586-b371-1ae5b39fe479'	System	23 Sep 2020 00:33:08
User entered 'No (N)'	System	23 Sep 2020 00:33:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-22T19:33:02', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'bb38296f-bf5f-4586-b371-1ae5b39fe479'	System	23 Sep 2020 00:33:08
User entered '22 Sep 2020 19:33'	System	23 Sep 2020 00:33:08

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
Data entry locked.	System	17 Sep 2020 22:00:10
User entered 'Day 7'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:18', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'aba508ff-c84d-45a8-9e39-d6b2ac4614f3'	System	24 Sep 2020 11:34:33
User entered 'None (0)'	System	24 Sep 2020 11:34:33

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'aba508ff-c84d-45a8-9e39-d6b2ac4614f3'	System	24 Sep 2020 11:34:33
User entered 'None (0)'	System	24 Sep 2020 11:34:33

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:20', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'aba508ff-c84d-45a8-9e39-d6b2ac4614f3'	System	24 Sep 2020 11:34:33
User entered 'None (0)'	System	24 Sep 2020 11:34:33

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'aba508ff-c84d-45a8-9e39-d6b2ac4614f3'	System	24 Sep 2020 11:34:33
User entered 'None (0)'	System	24 Sep 2020 11:34:33

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:23', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'aba508ff-c84d-45a8-9e39-d6b2ac4614f3'	System	24 Sep 2020 11:34:33
User entered 'None (0)'	System	24 Sep 2020 11:34:33

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:24', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'aba508ff-c84d-45a8-9e39-d6b2ac4614f3'	System	24 Sep 2020 11:34:33
User entered 'None (0)'	System	24 Sep 2020 11:34:33

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

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)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:26', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'aba508ff-c84d-45a8-9e39-d6b2ac4614f3'	System	24 Sep 2020 11:34:33
User entered 'No (N)'	System	24 Sep 2020 11:34:33

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-09-24T06:34:27', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'aba508ff-c84d-45a8-9e39-d6b2ac4614f3'	System	24 Sep 2020 11:34:33
User entered '24 Sep 2020 06:34'	System	24 Sep 2020 11:34:33

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 22:00:10

US3272195

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:23:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:50:20
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 22:00:10

US3272195

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:12:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:05
User entered 'Yes (Y)'		25 Sep 2020 15:35:14

US3272195

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:12:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:05
User entered '24 Sep 2020'		25 Sep 2020 15:35:14

US3272195

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:12:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:05
User entered 'Contact Made (CONTACT MADE)'		25 Sep 2020 15:35:14

US3272195

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:12:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:05
User entered empty.		25 Sep 2020 15:35:14

US3272195

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:12:47
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:10
User entered 'Yes (Y)'		25 Sep 2020 15:35:18

US3272195

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:12:47
User entered 'I'	System	25 Sep 2020 15:35:18

US3272195

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:16
User entered 'Yes (Y)'		01 Oct 2020 21:15:55

US3272195

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:16
User entered '1 Oct 2020'		01 Oct 2020 21:15:55

US3272195

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:16
User entered 'Contact Made (CONTACT MADE)'		01 Oct 2020 21:15:55

US3272195

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:16
User entered empty.		01 Oct 2020 21:15:55

US3272195

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:20
User entered 'Yes (Y)'		01 Oct 2020 21:16:00

US3272195

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:45
User entered 'I'	System	01 Oct 2020 21:16:00

US3272195

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:05:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:26
User entered 'Yes (Y)'		08 Oct 2020 18:47:27

US3272195

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:05:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:26
User entered '08 Oct 2020'		08 Oct 2020 18:47:27

US3272195

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:05:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:26
User entered 'Contact Made (CONTACT MADE)'		08 Oct 2020 18:47:27

US3272195

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:05:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:26
User entered empty.		08 Oct 2020 18:47:27

US3272195

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:05:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:11:30
User entered 'Yes (Y)'		08 Oct 2020 18:47:15

US3272195

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:05:17
User entered 'I'	System	08 Oct 2020 18:47:15

US3272195

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:29:15
User entered 'Yes (Y)'		15 Oct 2020 22:29:16

US3272195

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:29:15
User entered '15 Oct 2020'		15 Oct 2020 22:29:16

US3272195

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:29:15
User entered 'Clinic (Clinic)'		15 Oct 2020 22:29:16

US3272195

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User entered 'VISIT3'	System	15 Oct 2020 22:29:16

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:14
User entered 'Yes (Y)'		15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:14
User entered '15 Oct 2020'		15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:14
User entered '15:14'		15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User entered '15 Oct 2020 15:14'	System	15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:14
User entered '36.9' C		15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:14
User entered 'Oral (Oral)'		15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:14
User entered empty.		15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:14
User entered '81'		15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User entered 'bpm'	System	15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:14
User entered '18'		15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User entered 'breaths/min'	System	15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:14
User entered '140'		15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User entered 'mmHg'	System	15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:14
User entered '85'		15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User entered 'mmHg'	System	15 Oct 2020 22:30:54

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18

US3272195

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18

US3272195

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:19
User entered 'Yes (Y)'		15 Oct 2020 22:33:11

US3272195

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:19
User entered '15 Oct 2020'		15 Oct 2020 22:33:11

US3272195

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:24
User entered 'Yes (Y)'		15 Oct 2020 22:33:44

US3272195

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:24
User entered '15 Oct 2020'		15 Oct 2020 22:33:44

US3272195

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:30:24
User entered '15:26'		15 Oct 2020 22:33:44

US3272195

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User entered '15 Oct 2020 15:26'	System	15 Oct 2020 22:33:44

US3272195

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:39
User entered 'Yes (Y)'		15 Oct 2020 22:27:56

US3272195

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:18
User entered 'I'	System	15 Oct 2020 22:27:56

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 64'	System	20 Aug 2020 00:09:27

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-10-19T21:26:13', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2e6e0771-6b49-4b14-ad4c-aaef55675518'	System	20 Oct 2020 02:26:56
User entered 'No (N)'	System	20 Oct 2020 02:26:56

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-10-19T21:26:43', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2e6e0771-6b49-4b14-ad4c-aaef55675518'	System	20 Oct 2020 02:26:56
User entered 'No (N)'	System	20 Oct 2020 02:26:56

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-10-19T21:26:53', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '2e6e0771-6b49-4b14-ad4c-aaef55675518'	System	20 Oct 2020 02:26:56
User entered '19 Oct 2020 21:26:53'	System	20 Oct 2020 02:26:56

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
Data entry locked.	System	20 Aug 2020 00:09:27
User entered '19 Oct 2020 00:01'	System	20 Aug 2020 00:09:27

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
Data entry locked.	System	20 Aug 2020 00:09:27
User entered '23 Oct 2020 23:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 71'	System	20 Aug 2020 00:09:27

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered '26 Oct 2020 00:01'	System	20 Aug 2020 00:09:27

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:26:20
Data entry locked.	System	20 Aug 2020 00:09:27
User entered '30 Oct 2020 23:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 78'	System	20 Aug 2020 00:09:27

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:56:23', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da'	System	02 Nov 2020 12:58:03
User entered 'Yes (Y)'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:56:44', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da'	System	02 Nov 2020 12:58:03
User entered 'Yes (Y)'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:56:59', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da'	System	02 Nov 2020 12:58:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:05', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da'	System	02 Nov 2020 12:58:03
User entered 'Yes (Y)'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da' User entered '0'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da'	System	02 Nov 2020 12:58:03
User entered '1'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da'	System	02 Nov 2020 12:58:03
User entered '1'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da' User entered '0'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da' User entered '0'	System	02 Nov 2020 12:58:03
	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da' User entered '1'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da' User entered '0'	System	02 Nov 2020 12:58:03
	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da'	System	02 Nov 2020 12:58:03
User entered '1'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da' User entered '1'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da'	System	02 Nov 2020 12:58:03
User entered '1'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da' User entered '0'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da' User entered '0'	System	02 Nov 2020 12:58:03
	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da'	System	02 Nov 2020 12:58:03
User entered '1'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da' User entered '0'	System	02 Nov 2020 12:58:03
	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da' User entered '0'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da' User entered '0'	System	02 Nov 2020 12:58:03
	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da' User entered '0'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:30', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da'	System	02 Nov 2020 12:58:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:47', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da'	System	02 Nov 2020 12:58:03
User entered 'No (N)'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-02T06:57:54', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '998b30eb-711d-4b55-a19a-5ccf7d9263da'	System	02 Nov 2020 12:58:03
User entered '02 Nov 2020 06:57:54'	System	02 Nov 2020 12:58:03

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
Data entry locked.	System	20 Aug 2020 00:09:27
User entered '02 Nov 2020 00:01'	System	20 Aug 2020 00:09:27

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
Data entry locked.	System	20 Aug 2020 00:09:27
User entered '06 Nov 2020 23:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
Data entry locked.	System	20 Aug 2020 00:09:27
User entered 'Day 92'	System	20 Aug 2020 00:09:27

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:42:50', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered 'Yes (Y)'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:42:58', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered 'No (N)'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:03', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered 'Yes (Y)'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e' User entered '0'	System	16 Nov 2020 12:43:44
	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e' User entered '0'	System	16 Nov 2020 12:43:44
	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '1'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '1'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '1'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '1'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e' User entered '0'	System	16 Nov 2020 12:43:44
	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '0'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '0'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '0'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '0'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '0'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '1'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e' User entered '0'	System	16 Nov 2020 12:43:44
	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '0'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e' User entered '0'	System	16 Nov 2020 12:43:44
	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '0'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:23', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:30', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered 'No (N)'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-11-16T06:43:33', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8908de6a-0bfe-4879-9377-a7bf51ec4a4e'	System	16 Nov 2020 12:43:44
User entered '16 Nov 2020 06:43:33'	System	16 Nov 2020 12:43:44

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
Data entry locked.	System	20 Aug 2020 00:09:27
User entered '16 Nov 2020 00:01'	System	20 Aug 2020 00:09:27

US3272195

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:21
Data entry locked.	System	20 Aug 2020 00:09:27
User entered '20 Nov 2020 23:59'	System	20 Aug 2020 00:09:27

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2020-12-05T19:00:39', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '47825f63-5fa2-4c28-85c3-79ad60cf4b3f'	System	06 Dec 2020 01:00:53
User entered 'No (N)'	System	06 Dec 2020 01:00:53

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2020-12-05T19:00:43', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '47825f63-5fa2-4c28-85c3-79ad60cf4b3f'	System	06 Dec 2020 01:00:53
User entered 'No (N)'	System	06 Dec 2020 01:00:53

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-12-05T19:00:48', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '47825f63-5fa2-4c28-85c3-79ad60cf4b3f'	System	06 Dec 2020 01:00:53
User entered '05 Dec 2020 19:00:48'	System	06 Dec 2020 01:00:53

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2020-12-11T05:10:28', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '26f0eb48-a8df-4c78-b99c-e2be3cad82d3'	System	11 Dec 2020 11:10:43
User entered 'No (N)'	System	11 Dec 2020 11:10:43

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2020-12-11T05:10:35', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '26f0eb48-a8df-4c78-b99c-e2be3cad82d3'	System	11 Dec 2020 11:10:43
User entered 'No (N)'	System	11 Dec 2020 11:10:43

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-12-11T05:10:39', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '26f0eb48-a8df-4c78-b99c-e2be3cad82d3'	System	11 Dec 2020 11:10:43
User entered '11 Dec 2020 05:10:39'	System	11 Dec 2020 11:10:43

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2020-12-20T08:44:01', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'e2feed86-9ff4-472b-b8ee-698fee1fa265'	System	20 Dec 2020 14:44:12
User entered 'No (N)'	System	20 Dec 2020 14:44:12

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2020-12-20T08:44:06', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'e2feed86-9ff4-472b-b8ee-698fee1fa265'	System	20 Dec 2020 14:44:12
User entered 'No (N)'	System	20 Dec 2020 14:44:12

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-12-20T08:44:09', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'e2feed86-9ff4-472b-b8ee-698fee1fa265'	System	20 Dec 2020 14:44:12
User entered '20 Dec 2020 08:44:09'	System	20 Dec 2020 14:44:12

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2020-12-25T00:38:16', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '7a8c267a-8463-46e3-a755-66e76574c938'	System	25 Dec 2020 06:38:29
User entered 'No (N)'	System	25 Dec 2020 06:38:29

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2020-12-25T00:38:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '7a8c267a-8463-46e3-a755-66e76574c938'	System	25 Dec 2020 06:38:29
User entered 'No (N)'	System	25 Dec 2020 06:38:29

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2020-12-25T00:38:25', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '7a8c267a-8463-46e3-a755-66e76574c938'	System	25 Dec 2020 06:38:29
User entered '25 Dec 2020 00:38:25'	System	25 Dec 2020 06:38:29

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-01-01T00:01:26', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '798a1e19-cf92-4469-a985-9a643bd53b85'	System	01 Jan 2021 06:01:38
User entered 'No (N)'	System	01 Jan 2021 06:01:38

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-01-01T00:01:29', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '798a1e19-cf92-4469-a985-9a643bd53b85'	System	01 Jan 2021 06:01:38
User entered 'No (N)'	System	01 Jan 2021 06:01:38

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-01-01T00:01:32', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '798a1e19-cf92-4469-a985-9a643bd53b85'	System	01 Jan 2021 06:01:38
User entered '01 Jan 2021 00:01:32'	System	01 Jan 2021 06:01:38

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-01-11T09:33:50', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '197df6ef-587f-4f0d-8b63-5d0554107ef5'	System	11 Jan 2021 15:34:25
User entered 'No (N)'	System	11 Jan 2021 15:34:25

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-01-11T09:34:07', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '197df6ef-587f-4f0d-8b63-5d0554107ef5'	System	11 Jan 2021 15:34:25
User entered 'Yes (Y)'	System	11 Jan 2021 15:34:25

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-01-11T09:34:10', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '197df6ef-587f-4f0d-8b63-5d0554107ef5'	System	11 Jan 2021 15:34:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Jan 2021 15:34:25

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-01-11T09:34:13', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '197df6ef-587f-4f0d-8b63-5d0554107ef5'	System	11 Jan 2021 15:34:25
User entered '11 Jan 2021 09:34:13'	System	11 Jan 2021 15:34:25

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-01-15T14:22:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a10ced0c-6c30-4806-99f5-41589076637b'	System	15 Jan 2021 20:22:11
User entered 'No (N)'	System	15 Jan 2021 20:22:11

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-01-15T14:22:03', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a10ced0c-6c30-4806-99f5-41589076637b'	System	15 Jan 2021 20:22:11
User entered 'No (N)'	System	15 Jan 2021 20:22:11

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-01-15T14:22:07', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'a10ced0c-6c30-4806-99f5-41589076637b' User entered '15 Jan 2021 14:22:07'	System	15 Jan 2021 20:22:11
	System	15 Jan 2021 20:22:11

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-01-22T06:03:53', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'e522fdc3-176b-4c73-b24f-e56f7708893e'	System	22 Jan 2021 12:04:07
User entered 'No (N)'	System	22 Jan 2021 12:04:07

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-01-22T06:03:57', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'e522fdc3-176b-4c73-b24f-e56f7708893e'	System	22 Jan 2021 12:04:07
User entered 'No (N)'	System	22 Jan 2021 12:04:07

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-01-22T06:04:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'e522fdc3-176b-4c73-b24f-e56f7708893e'	System	22 Jan 2021 12:04:07
User entered '22 Jan 2021 06:04:00'	System	22 Jan 2021 12:04:07

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-01-30T22:35:19', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'c47e0622-4af7-48d9-a24e-10398f618b7e'	System	31 Jan 2021 04:35:28
User entered 'No (N)'	System	31 Jan 2021 04:35:28

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-01-30T22:35:23', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'c47e0622-4af7-48d9-a24e-10398f618b7e'	System	31 Jan 2021 04:35:28
User entered 'No (N)'	System	31 Jan 2021 04:35:28

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-01-30T22:35:26', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'c47e0622-4af7-48d9-a24e-10398f618b7e'	System	31 Jan 2021 04:35:28
User entered '30 Jan 2021 22:35:26'	System	31 Jan 2021 04:35:28

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-02-05T04:52:21', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '20ea8bbf-8777-44b5-a46f-24da2c11ea7a'	System	05 Feb 2021 10:52:32
User entered 'No (N)'	System	05 Feb 2021 10:52:32

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-02-05T04:52:26', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '20ea8bbf-8777-44b5-a46f-24da2c11ea7a'	System	05 Feb 2021 10:52:32
User entered 'No (N)'	System	05 Feb 2021 10:52:32

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-02-05T04:52:30', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '20ea8bbf-8777-44b5-a46f-24da2c11ea7a'	System	05 Feb 2021 10:52:32
User entered '05 Feb 2021 04:52:30'	System	05 Feb 2021 10:52:32

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-02-12T06:18:07', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '797847a1-1161-49c6-8e5a-9949a42ef069'	System	12 Feb 2021 12:18:18
User entered 'No (N)'	System	12 Feb 2021 12:18:18

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-02-12T06:18:11', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '797847a1-1161-49c6-8e5a-9949a42ef069'	System	12 Feb 2021 12:18:18
User entered 'No (N)'	System	12 Feb 2021 12:18:18

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-02-12T06:18:16', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '797847a1-1161-49c6-8e5a-9949a42ef069'	System	12 Feb 2021 12:18:18
User entered '12 Feb 2021 06:18:16'	System	12 Feb 2021 12:18:18

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-02-19T06:02:29', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '5c3be95e-878d-4df1-920b-19b6f6a94888'	System	19 Feb 2021 12:02:41
User entered 'No (N)'	System	19 Feb 2021 12:02:41

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-02-19T06:02:32', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '5c3be95e-878d-4df1-920b-19b6f6a94888'	System	19 Feb 2021 12:02:41
User entered 'No (N)'	System	19 Feb 2021 12:02:41

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-02-19T06:02:36', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '5c3be95e-878d-4df1-920b-19b6f6a94888'	System	19 Feb 2021 12:02:41
User entered '19 Feb 2021 06:02:36'	System	19 Feb 2021 12:02:41

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-03-01T14:55:59-06:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '1b064a98-7e8c-4733-a5e7-435d1ee797c3'	System	01 Mar 2021 20:56:10
User entered 'No (N)'	System	01 Mar 2021 20:56:10

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-03-01T14:56:01-06:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '1b064a98-7e8c-4733-a5e7-435d1ee797c3'	System	01 Mar 2021 20:56:10
User entered 'No (N)'	System	01 Mar 2021 20:56:10

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-03-01T14:56:05-06:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '1b064a98-7e8c-4733-a5e7-435d1ee797c3'	System	01 Mar 2021 20:56:10
User entered '01 Mar 2021 14:56:05'	System	01 Mar 2021 20:56:10

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-03-05T06:35:21-06:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b1a5e4d0-c6cf-4153-b773-480f1d96f115'	System	05 Mar 2021 12:35:35
User entered 'No (N)'	System	05 Mar 2021 12:35:35

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-03-05T06:35:25-06:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b1a5e4d0-c6cf-4153-b773-480f1d96f115'	System	05 Mar 2021 12:35:35
User entered 'No (N)'	System	05 Mar 2021 12:35:35

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-03-05T06:35:28-06:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'b1a5e4d0-c6cf-4153-b773-480f1d96f115'	System	05 Mar 2021 12:35:35
User entered '05 Mar 2021 06:35:28'	System	05 Mar 2021 12:35:35

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-03-12T06:02:45-06:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'bf28fc66-9d11-4b6c-9fa4-7c633188d7e9'	System	12 Mar 2021 12:03:00
User entered 'No (N)'	System	12 Mar 2021 12:03:00

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-03-12T06:02:52-06:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'bf28fc66-9d11-4b6c-9fa4-7c633188d7e9'	System	12 Mar 2021 12:03:00
User entered 'No (N)'	System	12 Mar 2021 12:03:00

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-03-12T06:02:55-06:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'bf28fc66-9d11-4b6c-9fa4-7c633188d7e9'	System	12 Mar 2021 12:03:00
User entered '12 Mar 2021 06:02:55'	System	12 Mar 2021 12:03:00

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-03-19T05:05:26-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8b3cfba1-00e4-41ad-b98b-5a215b31dea3'	System	19 Mar 2021 10:05:36
User entered 'No (N)'	System	19 Mar 2021 10:05:36

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-03-19T05:05:30-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8b3cfba1-00e4-41ad-b98b-5a215b31dea3'	System	19 Mar 2021 10:05:36
User entered 'No (N)'	System	19 Mar 2021 10:05:36

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-03-19T05:05:32-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '8b3cfba1-00e4-41ad-b98b-5a215b31dea3'	System	19 Mar 2021 10:05:36
User entered '19 Mar 2021 05:05:32'	System	19 Mar 2021 10:05:36

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-03-30T14:36:34-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '958701f7-c9bb-48cf-9267-2c66b746ba5c' User entered 'No (N)'	System	30 Mar 2021 19:36:41
	System	30 Mar 2021 19:36:41

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-03-30T14:36:36-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '958701f7-c9bb-48cf-9267-2c66b746ba5c'	System	30 Mar 2021 19:36:41
User entered 'No (N)'	System	30 Mar 2021 19:36:41

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-03-30T14:36:38-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '958701f7-c9bb-48cf-9267-2c66b746ba5c' User entered '30 Mar 2021 14:36:38'	System	30 Mar 2021 19:36:41
	System	30 Mar 2021 19:36:41

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-04-02T05:07:35-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '57f11a2f-c041-4e43-acc2-0207668bc840' User entered 'No (N)'	System	02 Apr 2021 10:07:46
	System	02 Apr 2021 10:07:46

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-04-02T05:07:38-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '57f11a2f-c041-4e43-acc2-0207668bc840'	System	02 Apr 2021 10:07:46
User entered 'No (N)'	System	02 Apr 2021 10:07:46

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-04-02T05:07:42-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '57f11a2f-c041-4e43-acc2-0207668bc840' User entered '02 Apr 2021 05:07:42'	System	02 Apr 2021 10:07:46
	System	02 Apr 2021 10:07:46

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-04-09T06:33:25-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '27410093-f137-40f0-8ed9-9113b50adedd' User entered 'No (N)'	System	09 Apr 2021 11:33:36
	System	09 Apr 2021 11:33:36

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-04-09T06:33:29-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '27410093-f137-40f0-8ed9-9113b50adedd' User entered 'No (N)'	System	09 Apr 2021 11:33:36

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-04-09T06:33:32-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '27410093-f137-40f0-8ed9-9113b50adedd' User entered '09 Apr 2021 06:33:32'	System	09 Apr 2021 11:33:36
	System	09 Apr 2021 11:33:36

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-04-19T22:13:24-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '13e84fa8-76c2-46d5-b07b-b1a7feacf209'	System	20 Apr 2021 03:13:37
User entered 'No (N)'	System	20 Apr 2021 03:13:37

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-04-19T22:13:28-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '13e84fa8-76c2-46d5-b07b-b1a7feacf209'	System	20 Apr 2021 03:13:37
User entered 'No (N)'	System	20 Apr 2021 03:13:37

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-04-19T22:13:32-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '13e84fa8-76c2-46d5-b07b-b1a7feacf209'	System	20 Apr 2021 03:13:37
User entered '19 Apr 2021 22:13:32'	System	20 Apr 2021 03:13:37

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-04-25T08:45:00-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'f8605b20-d881-4798-ac99-1f4cc4f67b01'	System	25 Apr 2021 13:45:11
User entered 'No (N)'	System	25 Apr 2021 13:45:11

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-04-25T08:45:03-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'f8605b20-d881-4798-ac99-1f4cc4f67b01'	System	25 Apr 2021 13:45:11
User entered 'No (N)'	System	25 Apr 2021 13:45:11

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-04-25T08:45:06-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: 'f8605b20-d881-4798-ac99-1f4cc4f67b01'	System	25 Apr 2021 13:45:11
User entered '25 Apr 2021 08:45:06'	System	25 Apr 2021 13:45:11

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[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 (9cc82256674b415e)', Time: '2021-04-30T06:11:05-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '79077d29-db17-440c-9f94-3f2296fdf80a' User entered 'No (N)'	System	30 Apr 2021 11:11:18
	System	30 Apr 2021 11:11:18

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

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 (9cc82256674b415e)', Time: '2021-04-30T06:11:10-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '79077d29-db17-440c-9f94-3f2296fdf80a'	System	30 Apr 2021 11:11:18
User entered 'No (N)'	System	30 Apr 2021 11:11:18

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-04-30T06:11:13-05:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '79077d29-db17-440c-9f94-3f2296fdf80a'	System	30 Apr 2021 11:11:18
User entered '30 Apr 2021 06:11:13'	System	30 Apr 2021 11:11:18

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:26:20

US3272195

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:23:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:26:20
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:26:20

US3272195

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:23:03

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)	30 Apr 2021 15:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-03-01T14:55:52-06:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '3d4eb05d-8c07-4e7b-9a31-073d2482ff38'	System	01 Mar 2021 20:55:58
User entered 'No (N)'	System	01 Mar 2021 20:55:58

US3272195

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:23:03

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9cc82256674b415e)', Time: '2021-03-01T14:55:55-06:00', User OID: 'PatientReportedOutcome (US3272195)', ODM File OID: '3d4eb05d-8c07-4e7b-9a31-073d2482ff38'	System	01 Mar 2021 20:55:58
User entered '01 Mar 2021 14:55:55'	System	01 Mar 2021 20:55:58

US3272195

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:35:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:20
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 18:21:08

US3272195

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:35:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:20
User entered '9 Nov 2020'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 18:21:08

US3272195

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:35:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:20
User entered 'Contact Made (CONTACT MADE)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 18:21:08

US3272195

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:35:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:20
User entered empty.	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 18:21:08

US3272195

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:35:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:28
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 18:21:12

US3272195

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:35:22
User entered 'I'	System	09 Nov 2020 18:21:12

US3272195

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:59
User entered 'Yes (Y)'		15 Dec 2020 20:11:55

US3272195

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:59
User entered '15 Dec 2020'		15 Dec 2020 20:11:55

US3272195

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:59
User entered 'Contact Made (CONTACT MADE)'		15 Dec 2020 20:11:55

US3272195

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:28:59
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 20:11:55

US3272195

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:29:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Dec 2020 20:11:57

US3272195

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:34:49
User entered 'I'	System	15 Dec 2020 20:11:57

US3272195

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:18:37
User entered 'Yes (Y)'	Whitney West (b) (4)	12 Jan 2021 23:51:56
	(b) (4)	

US3272195

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:18:37
User entered '12 Jan 2021'	Whitney West (b) (4)	12 Jan 2021 23:51:56
	(b) (4)	

US3272195

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:18:37
User entered 'Contact Made (CONTACT MADE)'	Whitney West (b) (4)	12 Jan 2021 23:51:56
	(b) (4)	

US3272195

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:18:37
User entered empty.	Whitney West (b) (4)	12 Jan 2021 23:51:56
	(b) (4)	

US3272195

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:19:12
User entered 'Yes (Y)'	Whitney West (b) (4)	12 Jan 2021 23:52:02
	(b) (4)	

US3272195

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:27:04
User entered 'I'	System	12 Jan 2021 23:52:02

US3272195

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:31:40
User entered 'Yes (Y)'		17 Feb 2021 16:11:02

US3272195

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:31:40
User entered '11 Feb 2021'		17 Feb 2021 16:11:02

US3272195

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:31:40
User entered 'Contact Made (CONTACT MADE)'		17 Feb 2021 16:11:02

US3272195

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:31:40
User entered empty.		17 Feb 2021 16:11:02

US3272195

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:31:51
User entered 'Yes (Y)'		17 Feb 2021 16:11:04

US3272195

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:11:56
User entered 'I'	System	17 Feb 2021 16:11:04

US3272195

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:13
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 17:36:09

US3272195

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:13
User entered '30 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 17:36:09

US3272195

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:13
User entered 'Clinic (Clinic)'	Ashley Bell (b) (4)	31 Mar 2021 17:36:09

US3272195

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	31 Mar 2021 17:36:09

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:17
User entered 'No (N)'	Ashley Bell (b) (4)	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:17
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:17
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:17
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:17
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:17
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:17
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:17
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:17
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:17
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 17:36:44

US3272195

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:21
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 17:36:17

US3272195

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:21
User entered '30 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 17:36:17

US3272195

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:26
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 17:36:32

US3272195

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:26
User entered '30 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 17:36:32

US3272195

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:32:26
User entered '14:43'	Ashley Bell (b) (4)	31 Mar 2021 17:36:32

US3272195

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User entered '30 Mar 2021 14:43'	System	31 Mar 2021 17:36:32

US3272195

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
User closed query 'Please update data or Day 239 when possible. Source is completed for this visit.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:23:40
Query 'Please update data or Day 239 when possible. Source is completed for this visit.' answered with 'updated' (Site from CRA).		19 Apr 2021 21:30:50
User opened query 'Please update data or Day 239 when possible. Source is completed for this visit.' (Site from CRA).		15 Apr 2021 20:33:24
DataPoint Verified.		15 Apr 2021 20:32:30
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 17:36:38

US3272195

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 17:36:38

US3272195

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 21:31:16

US3272195

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
User entered '12 Apr 2021'	(b) (4), (b) (6)	19 Apr 2021 21:31:16

US3272195

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Apr 2021 21:31:16

US3272195

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 21:31:16

US3272195

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 21:31:24

US3272195

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 21:31:24

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:23:03

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:10:21
User entered '02 Nov 2020'		03 Nov 2020 22:36:13

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:23:03

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:10:21
User entered '13:24'		03 Nov 2020 22:36:13

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:23:03

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:13
User entered '02 Nov 2020 13:24'	System	03 Nov 2020 22:36:13

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:23:03

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:10:21
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'		03 Nov 2020 22:36:13

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:23:03

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:10:21
User entered 'Yes (Y)'		03 Nov 2020 22:36:13

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '30 Oct 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:18:16
User entered '02 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:44:45
User entered '30 Oct 2020'		03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '0'		03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:18:16
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:41:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Nov 2020 19:21:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:18:16
User entered '37.6' C reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:44:45
User entered '37.6' F reason for change: Data Entry Error		03 Nov 2020 22:41:17
User entered missing code ND - Not Done.		03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:18:16
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:18:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:41:17
User entered 'Mild (Mild)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'		03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change:		03 Nov 2020 22:41:17
Data Entry Error		
User entered 'Moderate (Moderate)'		03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:41:17
User entered 'Moderate (Moderate)'		03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change: Data Entry Error		03 Nov 2020 22:41:17
User entered 'Moderate (Moderate)'		03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:18:16
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:41:17
User entered 'None (None)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:18:16
User entered 'Severe (Severe)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:18:16
User entered 'Severe (Severe)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:18:16
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	03 Nov 2020 22:38:42

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '31 Oct 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:19:10
User entered '03 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:19:10
User entered '97'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '99.0' F reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:19:10
User entered '101.2' F	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:19:10
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:19:10
User entered 'Mild (Mild)'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:19:10
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:19:10
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:19:10
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:19:10
User entered 'Severe (Severe)'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:19:10
User entered 'Severe (Severe)'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:19:10
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'		03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'		03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'		03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'		03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'		03 Nov 2020 22:44:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '01 Nov 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered '04 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered '94'	(b) (4), (b) (6)	06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	08 Nov 2020 19:21:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered '100.4' F	(b) (4), (b) (6)	06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change:		06 Nov 2020 23:16:36
Data Entry Error		
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:20:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 23:16:36
User entered empty.		06 Nov 2020 23:14:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '02 Nov 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:21:53
User entered '05 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '99' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:21:53
User entered '92'	(b) (4), (b) (6)	06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:26:44
User closed query 'Per CDM: It appears temperature of 37.6 F is low. Please review and update accordingly.' (Site from DM).		04 Jan 2021 14:45:45
Query 'Per CDM: It appears temperature of 37.6 F is low. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Jan 2021 17:40:58
DataPoint Un-verified.	(b) (4), (b) (6)	03 Jan 2021 17:40:44
User entered '37.6' C reason for change: Data Entry Error		03 Jan 2021 17:40:44
User opened query 'Per CDM: It appears temperature of 37.6 F is low. Please review and update accordingly.' (Site from DM).		30 Dec 2020 21:31:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '37.6' F reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:21:53
User entered '100.4' F	(b) (4), (b) (6)	06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:21:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change:		06 Nov 2020 23:33:59
Data Entry Error		
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:21:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:21:53
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:21:53
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:21:53
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:21:53
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:21:53
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:21:53
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error		06 Nov 2020 23:33:59
User entered empty.		06 Nov 2020 23:31:34

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '03 Nov 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:23:12
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '0'		06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '97' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:23:12
User entered '93'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '101.2' F reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:23:12
User entered '101.0' F	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'		06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:23:12
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:23:12
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'		06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:23:12
User entered 'Severe (Severe)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:23:12
User entered 'Severe (Severe)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:23:12
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:23:12
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:23:12
User entered 'Mild (Mild)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	06 Nov 2020 23:35:40

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Nov 2020 19:33:25
User entered 'Day 4 (Day 4)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '04 Nov 2020'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '94'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '100.4' F	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 00:24:41

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Nov 2020 19:33:25
User entered 'Day 5 (Day 5)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '05 Nov 2020'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
Query 'Per CDM: based on Symptom Log records for Days 5-67 with O2 saturation of 92%, 93% and 87% which are <=93%. Please advise if these were considered CS or NCS and make All appropriate updates (e.g. AE, Covid-19 Severity Assessment, etc.).' canceled (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:45:21
		10 Nov 2020 18:13:13
User opened query 'Per CDM: based on Symptom Log records for Days 5-67 with O2 saturation of 92%, 93% and 87% which are <=93%. Please advise if these were considered CS or NCS and make All appropriate updates (e.g. AE, Covid-19 Severity Assessment, etc.).' (Site from DM).		09 Nov 2020 00:22:50
Query 'Per CDM: based on Symptom Log records for Days 5-67 with O2 saturation of 92%, 93% and 87% which are <=93%. Please advise if these were considered CS or NCS and make All appropriate updates (e.g. AE, Covid-19 Severity Assessment, etc.).' canceled (Site from DM).		09 Nov 2020 00:22:30
User opened query 'Per CDM: based on Symptom Log records for Days 5-67 with O2 saturation of 92%, 93% and 87% which are <=93%. Please advise if these were considered CS or NCS and make All appropriate updates (e.g. AE, Covid-19 Severity Assessment, etc.).' (Site from DM).		09 Nov 2020 00:21:39
User entered '92'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '100.4' F	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 00:26:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Nov 2020 19:33:25
User entered 'Day 6 (Day 6)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '06 Nov 2020'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '93'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '101.0' F	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 00:27:28

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Nov 2020 19:33:25
User entered 'Day 7 (Day 7)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '07 Nov 2020'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '87'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '98.7' F	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Ashley Bell (b) (4)	07 Nov 2020 20:58:51

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '8 Nov 2020'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '0'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '95'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '98.1' F	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	(b) (4), (b) (6)	08 Nov 2020 19:33:25

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 11 (Day 11)'	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '9 Nov 2020'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '85'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '98.6' F	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Severe (Severe)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:08:15
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 18:01:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 18:01:59
User entered '10 Nov 2020' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 17:15:11
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '95' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	10 Nov 2020 18:01:59
User entered empty.	System	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered '98.8' F reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:13
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:01:59
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:15:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 13 (Day 13)'	Andrea Clement (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '11 Nov 2020'	Andrea Clement (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '0'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '90'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '98.6' F	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	11 Nov 2020 23:15:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 14 (Day 14)'	Andrea Clement (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '12 Nov 2020'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '0'	Andrea Clement (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '89'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '98.6' F	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:32:23

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 15 (Day 15)'	(b) (4), (b) (6)	14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '13 Nov 2020'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '0'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '95' reason for change: Data Entry Error		15 Nov 2020 15:48:22
User entered empty.		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	15 Nov 2020 15:48:22
User entered empty.	System	14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '98.6' F reason for change: Data Entry Error		15 Nov 2020 15:48:22
User entered empty.		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'		14 Nov 2020 15:57:57

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 16 (Day 16)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '14 Nov 2020'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '0'		15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '93'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '98.4' F	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 15:48:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 17 (Day 17)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '15 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '93'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '98.4' F	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:55:32

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 18 (Day 18)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '98'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '98.2' F	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Severe (Severe)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:56:59

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 19 (Day 19)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '17 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '96'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '97.9' F	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 17:58:29

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 20 (Day 20)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '96'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '98.4' F	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	(b) (4), (b) (6)	18 Nov 2020 21:35:11

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 21 (Day 21)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '19 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '0'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '96'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered '98.6' F	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'Mild (Mild)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:58:30
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 20:30:18

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 22 (Day 22)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '20 Nov 2020'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '0'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '98'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:01:12
User closed query 'please verify as 98.3 as per source' (Site from CRA).		18 Mar 2021 20:01:07
Query 'please verify as 98.3 as per source' answered with 'updated' (Site from CRA).		10 Mar 2021 15:08:12
User entered '98.3' F reason for change: Data Entry Error		10 Mar 2021 15:08:00
DataPoint Un-verified.		23 Feb 2021 15:35:51
DataPoint Verified.		23 Feb 2021 15:35:25
User opened query 'please verify as 98.3 as per source' (Site from CRA).		23 Feb 2021 15:31:15
User entered '98.2' F	Whitney West (b) (4)	20 Nov 2020 22:54:49
	(b) (4)	

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	20 Nov 2020 22:54:49

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 23 (Day 23)'	Kayla Flege (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '21 Nov 2020'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '0'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '99'	Kayla Flege (b) (4)	22 Nov 2020 17:52:22
	(b) (4)	

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '99.0' F	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4)	22 Nov 2020 17:52:22
	(b) (4)	

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 17:52:22

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 24 (Day 24)'	Kayla Flege (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '22 Nov 2020'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '0'	Kayla Flege (b) (4)	22 Nov 2020 18:35:38
	(b) (4)	

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '98'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '98.6' F	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4)	22 Nov 2020 18:35:38
	(b) (4)	

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:35:38

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 25 (Day 25)'	Andrea Clement (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '23 Nov 2020'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '0'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '98'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '97.9' F	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 18:11:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 26 (Day 26)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '24 Nov 2020'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '0'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '99'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '98.1' F	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	25 Nov 2020 18:02:03

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User closed query 'Per CDM: Per sponsor review Line #28 Symptom Day (Day 27) is duplicate to Line #26Symptom Day (Day 27)? Please review/update accordingly else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:11:57
User entered 'Day 27 (Day 27)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:44:32
Query 'Per CDM: Per sponsor review Line #28 Symptom Day (Day 27) is duplicate to Line #26Symptom Day (Day 27)? Please review/update accordingly else clarify. Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 18:40:27
User entered 'Day 26 (Day 26)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:40:14
User opened query 'Per CDM: Per sponsor review Line #28 Symptom Day (Day 27) is duplicate to Line #26Symptom Day (Day 27)? Please review/update accordingly else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:36:16
User entered 'Day 27 (Day 27)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '25 Nov 2020'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '0'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '98'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '97.7' F	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 28 (Day 28)'	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '26 Nov 2020'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '0'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '98'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '98.1' F reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:48:45
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)' reason for change: Data Entry Error	Andrea Clement (b) (4)	27 Nov 2020 15:49:42
User entered empty.	Andrea Clement (b) (4)	27 Nov 2020 15:46:58

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 29 (Day 29)'	Andrea Clement (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '27 Nov 2020'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '0'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '99'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '98.0' F	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 15:48:45

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 31 (Day 31)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '28 Nov 2020'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '0'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '99'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '98.3' F	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'Mild (Mild)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	28 Nov 2020 16:59:47

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered 'Day 32 (Day 32)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 22:47:03
User entered empty.	Whitney West (b) (4) (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User closed query 'Per CDM: Per sponsor review - Symptom Log Dates missing. Please review / verify and update missing dates between Days 31 and 32 of Symptom log, else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 15:46:13
Query 'Per CDM: Per sponsor review - Symptom Log Dates missing. Please review / verify and update missing dates between Days 31 and 32 of Symptom log, else clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:33:50
User opened query 'Per CDM: Per sponsor review - Symptom Log Dates missing. Please review / verify and update missing dates between Days 31 and 32 of Symptom log, else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 07:01:16
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '08 Dec 2020'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered '0'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User closed query 'Per CDM: It appears that O2 Saturation & Temperature for Day 41 were not provided. If not collected, please consider recording as 'Not Done'. Please enter Symptom Day in Symptom day field. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:52:21
Query 'Per CDM: It appears that O2 Saturation & Temperature for Day 41 were not provided. If not collected, please consider recording as 'Not Done'. Please enter Symptom Day in Symptom day field. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 22:47:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 22:47:03
User opened query 'Per CDM: It appears that O2 Saturation & Temperature for Day 41 were not provided. If not collected, please consider recording as 'Not Done'. Please enter Symptom Day in Symptom day field. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:37:44
User entered empty.	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User entered '%'	System	07 Jan 2021 22:47:03
User entered empty.	System	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 22:47:03
User entered empty.	Whitney West (b) (4) (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:23:03

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:35:25
User entered 'None (None)'	Whitney West (b) (4)	09 Dec 2020 00:04:14

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:23:03

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:47
User entered '02 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 22:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:23:03

[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 20:55:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 22:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:23:03

[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 20:55:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:47
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)	08 Nov 2020 10:56:04
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 'confirm' (Site from System).	Ashley Bell (b) (4)	07 Nov 2020 00:30:57
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	07 Nov 2020 00:09:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:09:02
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 22:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:23:03

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:47
User entered '02 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 22:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:23:03

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:47
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	03 Nov 2020 22:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:23:03

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:47
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 22:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:23:03

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 20:55:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:47
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	03 Nov 2020 22:46:35
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	03 Nov 2020 22:46:10
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 22:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:23:03

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:47
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 22:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:23:03

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:46:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 22:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:23:03

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:41
User entered '1'	System	07 Nov 2020 00:09:02
User entered '0'	System	03 Nov 2020 22:46:10

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

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 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

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 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:29:07
User closed query 'Please verify as symptom log notes that there were multiple dates that it was at or below 93%' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:29:06
Query 'Please verify as symptom log notes that there were multiple dates that it was at or below 93%' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4)	24 Nov 2020 15:58:53
User entered 'Yes (Y)' reason for change: New Information	Kayla Flege (b) (4)	24 Nov 2020 15:58:47
User opened query 'Please verify as symptom log notes that there were multiple dates that it was at or below 93%' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:49:14
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 16:00:13
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	14 Nov 2020 16:00:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 20:56:35
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:29:10
User closed query 'Please verify as symptom log notes first date subject was at or below 93% was 05Nov2020' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:29:09
Query 'Please verify as symptom log notes first date subject was at or below 93% was 05Nov2020' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4)	24 Nov 2020 15:58:56
User entered '5 Nov 2020' reason for change: New Information	(b) (4)	24 Nov 2020 15:58:47
User opened query 'Please verify as symptom log notes first date subject was at or below 93% was 05Nov2020' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:49:53
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 16:00:13
User entered empty; reason for change New Information	(b) (4), (b) (6)	14 Nov 2020 16:00:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered '07 Nov 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 20:56:35
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:29:13
User closed query 'Please verify as symptom log notes last date subject was at or below 93% was 15Nov2020' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:29:12
Query 'Please verify as symptom log notes last date subject was at or below 93% was 15Nov2020' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4)	24 Nov 2020 15:59:00
DataPoint Un-verified.	(b) (4)	
	Kayla Flege (b) (4)	24 Nov 2020 15:58:47
User entered '15 Nov 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	24 Nov 2020 15:58:47
User opened query 'Please verify as symptom log notes last date subject was at or below 93% was 15Nov2020' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:50:17
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:29:16
User closed query 'Please verify as symptom log notes lowest value of 85%' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:29:15
Query 'Please verify as symptom log notes lowest value of 85%' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4)	24 Nov 2020 15:59:03
User entered '85' reason for change: New Information	Kayla Flege (b) (4)	24 Nov 2020 15:58:47
User opened query 'Please verify as symptom log notes lowest value of 85%' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:50:34
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 16:00:13
User entered empty; reason for change New Information	(b) (4), (b) (6)	14 Nov 2020 16:00:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered '87' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 20:56:51
User entered '93' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 20:56:35
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
Query 'Per CDM: based on Symptom Log records for Days 5-67 with O2 saturation of 92%, 93% and 87% which are <=93%, please confirm response if accurate or update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 00:19:50
User opened query 'Per CDM: based on Symptom Log records for Days 5-67 with O2 saturation of 92%, 93% and 87% which are <=93%, please confirm response if accurate or update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 11:00:16
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:29:24
DataPoint Un-verified.		14 Nov 2020 16:00:13
User entered 'No (N)' reason for change: Data Entry Error		14 Nov 2020 16:00:13
DataPoint Verified.		10 Nov 2020 18:13:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 18:23:52
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:29:24
DataPoint Un-verified.		14 Nov 2020 16:00:13
User entered empty; reason for change New Information		14 Nov 2020 16:00:13
DataPoint Verified.		10 Nov 2020 18:13:57
User entered '7 Nov 2020' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 18:23:52
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:29:24
DataPoint Un-verified.		14 Nov 2020 16:00:13
User entered 'No (N)' reason for change: New Information		14 Nov 2020 16:00:13
DataPoint Verified.		10 Nov 2020 18:13:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 18:23:52
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:29:24
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 16:00:13
User entered empty; reason for change New Information	(b) (4), (b) (6)	14 Nov 2020 16:00:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered '7 Nov 2020' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 18:23:52
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[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 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:29:24
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 16:00:13
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	14 Nov 2020 16:00:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 18:23:52
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:29:24
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 16:00:13
User entered empty; reason for change New Information	(b) (4), (b) (6)	14 Nov 2020 16:00:13
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered '7 Nov 2020' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 18:23:52
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:23:03

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:55:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:09:27

US3272195

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:23:03

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:06
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:53:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 22:53:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:53:29
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:46:53
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 22:46:53

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:23:03

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Please confirm the date of collection for Day 3 saliva Visit as it was updated several times. Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:45:10
Query 'Per GCL Lab Reconciliation: Saliva: Please confirm the date of collection for Day 3 saliva Visit as it was updated several times. Thank you. ' answered with 'UPDATED' (Site from DM).	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 16:05:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Please confirm the date of collection for Day 3 saliva Visit as it was updated several times. Thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 04:29:20
User accepted default value 'Day 3 (Day 3)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:23:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:24:36
User entered 'Yes (Y)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:23:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:43:32
User closed query 'Per GCL Lab Reconciliation: Saliva: Please consider to review and confirm the correct Date of collection in query response. Thank you. ' (Site from DM).		14 Dec 2020 08:45:15
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05,06NOV2020 is recorded under Illness Visit Day 3,5 in EDC, however the same 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).		14 Dec 2020 08:45:08
Query 'Per GCL Lab Reconciliation: Saliva: Please consider to review and confirm the correct Date of collection in query response. Thank you. ' answered with 'UPDATED CORRECT INFORMATION' (Site from DM).	Kayla Flege (b) (4)	11 Dec 2020 16:05:50
DataPoint Un-verified.	Kayla Flege (b) (4)	11 Dec 2020 16:05:40
User entered '04 Nov 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 16:05:40
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05,06NOV2020 is recorded under Illness Visit Day 3,5 in EDC, however the same 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 'ALL SAMPLES HAVE BEEN SENT' (Site from DM).	Kayla Flege (b) (4)	11 Dec 2020 16:05:04
User opened query 'Per GCL Lab Reconciliation: Saliva: Please consider to review and confirm the correct Date of collection in query response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 03:03:29

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:23:03

Date of Collection

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 05,06NOV2020 is recorded under Illness Visit Day 3,5 in EDC, however the same 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)	04 Dec 2020 10:59:11
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 05NOV2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 17:59:09
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 05NOV2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 04:54:02
User entered '05 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 21:33:39
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 05NOV2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 21:33:30
User entered '4 Nov 2020' reason for change: Data Entry Error	Andrea Clement (b) (4)	12 Nov 2020 09:50:15
DataPoint Verified.	Andrea Clement (b) (4)	11 Nov 2020 23:13:35
User entered '05 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 23:13:35
	(b) (4)	10 Nov 2020 18:24:36
	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:23:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:23:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:09
DataPoint Un-verified.	Andrea Clement (b) (4)	11 Nov 2020 23:13:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 23:13:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:24:36
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:23:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Please provide the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:10:16
Query 'Per GCL Lab Reconciliation Requery: Saliva: Please provide the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD. ' answered with 'sample was shipped' (Site from DM).		03 Feb 2021 21:40:15
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Please provide the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD. ' (Site from DM).		19 Jan 2021 12:02:36
User closed query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 06NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).		19 Jan 2021 12:02:36
Query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 06NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'sample shipped' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 14:28:10
User opened query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 06NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).		09 Jan 2021 17:02:10
DataPoint Verified.		20 Nov 2020 17:59:09

PRODUCTION RELEASE (v12.003
EAB) (1725)

2641 of 3760

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:23:03

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Clement (b) (4)	11 Nov 2020 23:13:35
	(b) (4)	
User entered '6 Nov 2020' reason for change: Data Entry Error	Andrea Clement (b) (4)	11 Nov 2020 23:13:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:24:36
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:23:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:23:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:09
DataPoint Un-verified.	Andrea Clement (b) (4)	11 Nov 2020 23:13:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 23:13:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:24:36
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:23:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:09
DataPoint Un-verified.	Andrea Clement (b) (4)	11 Nov 2020 23:13:35
User entered '8 Nov 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 23:13:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:24:36
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:23:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:23:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:09
DataPoint Un-verified.	Andrea Clement (b) (4)	11 Nov 2020 23:13:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 23:13:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:24:36
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:23:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:45:37
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'THIS IS DATE SAMPLE WAS COLLECTED BY PATIENT' (Site from DM).	Kayla Flege (b) (4)	11 Dec 2020 16:06:19
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 02:56:07
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:09
DataPoint Un-verified.	Andrea Clement (b) (4)	11 Nov 2020 23:13:35
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 23:13:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:24:36
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:23:03

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17NOV2020 is recorded under Illness Visit Day 14 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 12:24:48
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17NOV2020 is recorded under Illness Visit Day 14 in EDC, however the same 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 'all samples have been shipped' (Site from DM).	Kayla Flege (b) (4)	18 Dec 2020 22:32:38
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17NOV2020 is recorded under Illness Visit Day 14 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 07:45:47
User accepted default value 'Day 14 (Day 14)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:23:03

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:24:05
DataPoint Un-verified.	Kayla Flege (b) (4)	11 Dec 2020 16:08:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 16:08:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:24:36
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:23:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:24:08
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated "30NOV2020" is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		14 Dec 2020 09:36:40
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is reported under Illness visit in PPD Central lab, however the data is 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. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:45:53
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated "30NOV2020" is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'WILL UPDATE' (Site from DM).	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 16:09:27
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is reported under Illness visit in PPD Central lab, however the data is 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. Else clarify, thank you. ' answered with 'THIS IS THE CORRECT SAMPLE COLLECTION DAY' (Site from DM).	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 16:08:39
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 16:08:23
User entered '17 Nov 2020' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 16:08:23

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:23:03

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated "30NOV2020" is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 08:01:53
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15NOV2020 is reported under Illness visit in PPD Central lab, however the data is 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. Else clarify, thank you. ' (Site from DM).		27 Nov 2020 04:37:42
DataPoint Verified.		10 Nov 2020 18:24:36
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:23:03

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 is recorded under Illness Visit Day 21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 12:26:51
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 is recorded under Illness Visit Day 21 in EDC, however the same 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 'all samples have been shipped. no samples at site.' (Site from DM).	Kayla Flege (b) (4) (b) (4)	18 Dec 2020 22:33:16
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 24NOV2020 is recorded under Illness Visit Day 21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 07:45:59
User accepted default value 'Day 21 (Day 21)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:23:03

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:23:33
DataPoint Un-verified.	Kayla Flege (b) (4)	11 Dec 2020 16:09:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 16:09:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:24:36
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:23:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:23:35
DataPoint Un-verified.	Kayla Flege (b) (4)	11 Dec 2020 16:10:14
User entered '24 Nov 2020' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 16:10:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:24:36
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:23:03

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:23:03

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:23:05
DataPoint Un-verified.	Kayla Flege (b) (4)	11 Dec 2020 16:10:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 16:10:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:24:36
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:23:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:23:08
DataPoint Un-verified.	Kayla Flege (b) (4)	11 Dec 2020 16:10:33
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	11 Dec 2020 16:10:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:24:36
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:10:57

US3272195

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:45
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:54:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 22:54:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:54:22
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:47:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:47:42
User entered 'Yes (Y)'		02 Nov 2020 20:06:34

US3272195

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:45
User entered '02 Nov 2020' reason for change: Data Entry Error		03 Nov 2020 22:54:22
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:47:42
User entered '02 Nov 2020'		02 Nov 2020 20:06:34

US3272195

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:45
User entered 'Clinic (Clinic)' reason for change: Data Entry Error		03 Nov 2020 22:54:22
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:47:42
User entered 'Clinic (Clinic)'		02 Nov 2020 20:06:34

US3272195

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	03 Nov 2020 22:54:22
User entered empty.	System	03 Nov 2020 22:47:42
User entered 'SICKD1'	System	02 Nov 2020 20:06:34

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:04
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:55:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 22:55:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:55:17
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:48:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:48:49
User entered 'Yes (Y)'		02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:04
User entered '02 Nov 2020' reason for change: Data Entry Error		03 Nov 2020 22:55:17
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:48:49
User entered '02 Nov 2020'		02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:04
User entered '13:24' reason for change: Data Entry Error		03 Nov 2020 22:55:17
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:48:49
User entered '13:24'		02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User entered '02 Nov 2020 13:24'	System	03 Nov 2020 22:55:17
User entered empty.	System	03 Nov 2020 22:48:49
User entered '02 Nov 2020 13:24'	System	02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:04
DataPoint set to visible.	System	03 Nov 2020 22:54:22
DataPoint set to invisible.	System	03 Nov 2020 22:47:42
User entered '154' cm	(b) (4), (b) (6)	02 Nov 2020 20:10:55
DataPoint set to visible.	System	02 Nov 2020 20:06:34

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Weight (.xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:04
DataPoint set to visible.	System	03 Nov 2020 22:54:22
DataPoint set to invisible.	System	03 Nov 2020 22:47:42
User entered '74.8' kg	(b) (4), (b) (6)	02 Nov 2020 20:10:55
DataPoint set to visible.	System	02 Nov 2020 20:06:34

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:04
User entered '37.6' C reason for change: Data Entry Error		03 Nov 2020 22:55:17
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:48:49
User entered '37.6' C		02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:04
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 22:55:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Nov 2020 22:55:29
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:55:29
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 22:55:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:48:49
User entered 'Oral (Oral)'		02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:04
User entered empty.		02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:04
User entered '101' reason for change: Data Entry Error		03 Nov 2020 22:55:17
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:48:49
User entered '101'		02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Nov 2020 22:55:17
User entered empty.	System	03 Nov 2020 22:48:49
User entered 'bpm'	System	02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:04
User entered '18' reason for change: Data Entry Error		03 Nov 2020 22:55:17
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:48:49
User entered '18'		02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Nov 2020 22:55:17
User entered empty.	System	03 Nov 2020 22:48:49
User entered 'breaths/min'	System	02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:04
User entered '108' reason for change: Data Entry Error		03 Nov 2020 22:55:17
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:48:49
User entered '108'		02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Nov 2020 22:55:17
User entered empty.	System	03 Nov 2020 22:48:49
User entered 'mmHg'	System	02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:04
User entered '81' reason for change: Data Entry Error		03 Nov 2020 22:55:17
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:48:49
User entered '81'		02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Nov 2020 22:55:17
User entered empty.	System	03 Nov 2020 22:48:49
User entered 'mmHg'	System	02 Nov 2020 20:10:55

US3272195

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:11
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:55:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 22:55:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:55:43
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:49:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:49:12
User entered 'Yes (Y)'		02 Nov 2020 20:11:10

US3272195

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:11
User entered '02 Nov 2020' reason for change: Data Entry Error		03 Nov 2020 22:55:43
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:49:12
User entered '02 Nov 2020'		02 Nov 2020 20:11:10

US3272195

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:23:03

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:22
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:55:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 22:55:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:55:51
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:49:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:49:33
User entered 'Yes (Y)'		02 Nov 2020 20:11:31

US3272195

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:23:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:22
User entered '02 Nov 2020' reason for change: Data Entry Error		03 Nov 2020 22:55:59
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:49:33
User entered '02 Nov 2020'		02 Nov 2020 20:11:31

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:20:48
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: It appears PPD central lab has a SARS-CoV-2 serum sample dated 30 NOV 2020 as a Convalescence Visit Day 28, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 06:29:55
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: It appears PPD central lab has a SARS-CoV-2 serum sample dated 30 NOV 2020 as a Convalescence Visit Day 28, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' answered with 'This page you have the query on is the Convalescence Visit Day 28. and the immunogenicity is located on page 4. ' (Site from DM).	Kayla Flege (b) (4) (b) (4)	14 Dec 2020 20:53:50
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: It appears PPD central lab has a SARS-CoV-2 serum sample dated 30 NOV 2020 as a Convalescence Visit Day 28, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:04:47
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 30 NOV 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:04:47

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 30 NOV 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'ALL SAMPLES HAVE SHIPPED.' (Site from DM).	Kayla Flege (b) (4)	11 Dec 2020 16:11:25
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 30 NOV 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 10:00:52
DataPoint Un-verified.	Kayla Flege (b) (4)	30 Nov 2020 23:19:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	30 Nov 2020 23:19:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:30
User closed query 'Data is required. Please complete.' (Site from System).		08 Nov 2020 11:00:59
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).		03 Nov 2020 22:56:31
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:50:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:50:47
User entered 'Yes (Y)'		03 Nov 2020 22:32:31

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:20:48
DataPoint Un-verified.	Kayla Flege (b) (4)	30 Nov 2020 23:19:47
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	30 Nov 2020 23:19:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:30
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:50:47
User entered '02 Nov 2020' reason for change: Data Entry Error		03 Nov 2020 22:32:58
User entered '30 Oct 2020'		03 Nov 2020 22:32:31

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:20:48
DataPoint Un-verified.	Kayla Flege (b) (4)	30 Nov 2020 23:19:47
User entered 'Clinic (Clinic)' reason for change:	(b) (4)	
Data Entry Error	Kayla Flege (b) (4)	30 Nov 2020 23:19:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:15:30
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:50:47
User entered 'Clinic (Clinic)'		03 Nov 2020 22:32:31

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	30 Nov 2020 23:19:47
User entered empty.	System	03 Nov 2020 22:50:47
User entered 'SICKD28'	System	03 Nov 2020 22:32:31

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:15
DataPoint Un-verified.	Kayla Flege (b) (4)	30 Nov 2020 23:20:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	30 Nov 2020 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:34
DataPoint Un-verified.		10 Nov 2020 18:16:10
DataPoint Verified.		10 Nov 2020 18:15:44
User closed query 'Data is required. Please complete.' (Site from System).		08 Nov 2020 11:01:16
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).		03 Nov 2020 22:56:42
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:51:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:51:41
User entered 'Yes (Y)'		03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:15
DataPoint Un-verified.	Kayla Flege (b) (4)	30 Nov 2020 23:20:40
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	30 Nov 2020 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:34
DataPoint Un-verified.		10 Nov 2020 18:16:12
DataPoint Verified.		10 Nov 2020 18:15:44
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:51:41
User entered '02 Nov 2020'		03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:15
DataPoint Un-verified.	Kayla Flege (b) (4)	30 Nov 2020 23:20:40
User entered '16:28' reason for change: Data Entry Error	(b) (4)	30 Nov 2020 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:34
DataPoint Un-verified.		10 Nov 2020 18:16:13
DataPoint Verified.		10 Nov 2020 18:15:44
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:51:41
User entered '13:24'		03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User entered '30 Nov 2020 16:28'	System	30 Nov 2020 23:20:40
User entered empty.	System	03 Nov 2020 22:51:41
User entered '02 Nov 2020 13:24'	System	03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:15
User entered '152.5' cm reason for change: Data Entry Error	Kayla Flege (b) (4)	30 Nov 2020 23:20:40
DataPoint set to visible.	System	30 Nov 2020 23:19:47
DataPoint set to invisible.	System	03 Nov 2020 22:50:47
User entered '154' cm	(b) (4), (b) (6)	03 Nov 2020 22:34:27
DataPoint set to visible.	System	03 Nov 2020 22:32:31

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:15
User entered '75.0' kg reason for change: Data Entry Error	Kayla Flege (b) (4)	30 Nov 2020 23:20:40
DataPoint set to visible.	System	30 Nov 2020 23:19:47
DataPoint set to invisible.	System	03 Nov 2020 22:50:47
User entered '74.8' kg	(b) (4), (b) (6)	03 Nov 2020 22:34:27
DataPoint set to visible.	System	03 Nov 2020 22:32:31

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:15
DataPoint Un-verified.	Kayla Flege (b) (4)	30 Nov 2020 23:20:40
User entered '36.6' C reason for change: Data Entry Error	(b) (4)	30 Nov 2020 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:34
DataPoint Un-verified.		10 Nov 2020 18:16:17
DataPoint Verified.		10 Nov 2020 18:15:44
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:51:41
User entered '37.6' C		03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:15
DataPoint Un-verified.	Kayla Flege (b) (4)	30 Nov 2020 23:20:40
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	30 Nov 2020 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:34
DataPoint Un-verified.		10 Nov 2020 18:16:15
DataPoint Verified.		10 Nov 2020 18:15:44
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:51:41
User entered 'Oral (Oral)'		03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:34
DataPoint Un-verified.		10 Nov 2020 18:16:20
DataPoint Verified.		10 Nov 2020 18:15:44
User entered empty.		03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:15
DataPoint Un-verified.	Kayla Flege (b) (4)	30 Nov 2020 23:20:40
User entered '84' reason for change: Data Entry Error	(b) (4)	30 Nov 2020 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:34
DataPoint Un-verified.		10 Nov 2020 18:16:26
DataPoint Verified.		10 Nov 2020 18:15:44
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:51:41
User entered '101'		03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Nov 2020 23:20:40
User entered empty.	System	03 Nov 2020 22:51:41
User entered 'bpm'	System	03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:15
DataPoint Un-verified.	Kayla Flege (b) (4)	30 Nov 2020 23:20:40
User entered '16' reason for change: Data Entry Error	(b) (4)	30 Nov 2020 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:34
DataPoint Un-verified.		10 Nov 2020 18:16:23
DataPoint Verified.		10 Nov 2020 18:15:44
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:51:41
User entered '18'		03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Nov 2020 23:20:40
User entered empty.	System	03 Nov 2020 22:51:41
User entered 'breaths/min'	System	03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:15
DataPoint Un-verified.	Kayla Flege (b) (4)	30 Nov 2020 23:20:40
User entered '110' reason for change: Data Entry Error	(b) (4)	30 Nov 2020 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:34
DataPoint Un-verified.		10 Nov 2020 18:16:30
DataPoint Verified.		10 Nov 2020 18:15:44
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:51:41
User entered '108'		03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Nov 2020 23:20:40
User entered empty.	System	03 Nov 2020 22:51:41
User entered 'mmHg'	System	03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:15
DataPoint Un-verified.	Kayla Flege (b) (4)	30 Nov 2020 23:20:40
User entered '64' reason for change: Data Entry Error	(b) (4)	30 Nov 2020 23:20:40
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:34
DataPoint Un-verified.		10 Nov 2020 18:16:32
DataPoint Verified.		10 Nov 2020 18:15:44
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:51:41
User entered '81'		03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Nov 2020 23:20:40
User entered empty.	System	03 Nov 2020 22:51:41
User entered 'mmHg'	System	03 Nov 2020 22:34:27

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:27
DataPoint Un-verified.	Kayla Flege (b) (4)	15 Dec 2020 22:25:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	15 Dec 2020 22:25:44
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:26
User closed query 'Data is required. Please complete.' (Site from System).		08 Nov 2020 11:01:20
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).		03 Nov 2020 22:56:53
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 22:52:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 22:52:00
User entered 'Yes (Y)'		03 Nov 2020 22:34:43

US3272195

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:27
DataPoint Un-verified.	Kayla Flege (b) (4)	15 Dec 2020 22:25:44
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	15 Dec 2020 22:25:44
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:26
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:52:00
User entered '02 Nov 2020'		03 Nov 2020 22:34:43

US3272195

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:37
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: It appears PPD central lab has a SARS-CoV-2 serum sample dated 30 NOV 2020 as a Convalescence Visit Day 28, but there is no SARS-CoV-2 serum sample record for Convalescence Visit Day 28 in EDC with this date. Please reconcile and update the data else clarify' (Site from DM).		18 Dec 2020 07:27:22
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: It appears PPD central lab has a SARS-CoV-2 serum sample dated 30 NOV 2020 as a Convalescence Visit Day 28, but there is no SARS-CoV-2 serum sample record for Convalescence Visit Day 28 in EDC with this date. Please reconcile and update the data else clarify' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	15 Dec 2020 22:26:01
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	15 Dec 2020 22:25:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	15 Dec 2020 22:25:57
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: It appears PPD central lab has a SARS-CoV-2 serum sample dated 30 NOV 2020 as a Convalescence Visit Day 28, but there is no SARS-CoV-2 serum sample record for Convalescence Visit Day 28 in EDC with this date. Please reconcile and update the data else clarify' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 06:27:31
DataPoint Verified.		20 Nov 2020 17:59:20
User closed query 'Data is required. Please complete.' (Site from System).		08 Nov 2020 11:01:24
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).		03 Nov 2020 22:57:06
User opened query 'Data is required. Please complete.' (Site from System).		03 Nov 2020 22:52:15
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:52:15

PRODUCTION RELEASE (v12.003
EAB) (1725)

2708 of 3760

US3272195

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 16:23:03

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 22:35:05

US3272195

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 16:23:03

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:22:37
DataPoint Un-verified.	Kayla Flege (b) (4)	15 Dec 2020 22:25:57
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	15 Dec 2020 22:25:57
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 17:59:20
User entered empty; reason for change Data Entry Error		03 Nov 2020 22:52:15
User entered '02 Nov 2020'		03 Nov 2020 22:35:05

US3272195

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

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:06
User entered 'Yes (Y)'		22 Jan 2021 20:46:34

US3272195

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

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:06
User entered '14 Jan 2021'		22 Jan 2021 20:46:34

US3272195

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

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:06
User entered 'Clinic (Clinic)'		22 Jan 2021 20:46:34

US3272195

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

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 20:46:34

US3272195

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

Form: Unblinding

Generated On: 09 Jun 2021 16:23:03

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:14
User entered '14 Jan 2021'		22 Jan 2021 20:47:03

US3272195

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

Form: Unblinding

Generated On: 09 Jun 2021 16:23:03

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:11:57

US3272195

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

Form: Unblinding

Generated On: 09 Jun 2021 16:23:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:14
User entered 'Yes (Y)'		22 Jan 2021 20:47:03

US3272195

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

Form: Unblinding

Generated On: 09 Jun 2021 16:23:03

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:14
User closed query 'PER CDM: 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 12:50:46
Query 'PER CDM: 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 'Data has been corrected' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:18:38
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error		08 Apr 2021 18:18:22
User opened query 'PER CDM: 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).		08 Apr 2021 12:25:25
User entered 'AMENDMENT 5 (AMENDMENT 5)'	System	10 Mar 2021 16:55:28
WR# 5295537		
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:11:57

US3272195

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

Form: Unblinding

Generated On: 09 Jun 2021 16:23:03

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:14
User entered '14 Jan 2021'		22 Jan 2021 20:47:03

US3272195

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

Form: Unblinding

Generated On: 09 Jun 2021 16:23:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:14
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Jan 2021 20:47:03

US3272195

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

Form: Unblinding

Generated On: 09 Jun 2021 16:23:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:14
User entered 'Placebo (Placebo)'		22 Jan 2021 20:47:03

US3272195

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

Form: Unblinding

Generated On: 09 Jun 2021 16:23:03

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:14
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Jan 2021 20:47:03

US3272195

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

Form: Unblinding

Generated On: 09 Jun 2021 16:23:03

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:47:03

US3272195

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

Form: Unblinding

Generated On: 09 Jun 2021 16:23:03

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered '1'	System	22 Jan 2021 20:47:03

US3272195

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

Form: Unblinding

Generated On: 09 Jun 2021 16:23:03

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'I'	System	22 Jan 2021 20:47:03

US3272195

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:18
User entered missing code ND - Not Done.		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:20
User entered missing code ND - Not Done.		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered empty.	System	22 Jan 2021 20:48:46
DataPoint set to visible.	System	22 Jan 2021 20:47:03

US3272195

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:18
User entered missing code ND - Not Done.		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:20
User entered missing code ND - Not Done.		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered empty.	System	22 Jan 2021 20:48:46
DataPoint set to visible.	System	22 Jan 2021 20:47:03

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User accepted default value 'Pre-Dose (PREDOSE)'		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered 'Yes (Y)'		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '14 Jan 2021'		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '16:06'		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered '14 Jan 2021 16:06'	System	22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '36.4' C		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered 'Oral (Oral)'		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered empty.		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '75'		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'bpm'	System	22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '16'		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'breaths/min'	System	22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '130'		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'mmHg'	System	22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '87'		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'mmHg'	System	22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:18
User entered missing code ND - Not Done.		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:44:20
User entered missing code ND - Not Done.		22 Jan 2021 20:48:46

US3272195

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:23:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered empty.	System	22 Jan 2021 20:48:46
DataPoint set to visible.	System	22 Jan 2021 20:47:03

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User accepted default value 'Post-Dose (POSTDOSE)'		22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered 'Yes (Y)'		22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '14 Jan 2021'		22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '17:31'		22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered '14 Jan 2021 17:31'	System	22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '37.0' C		22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered 'Oral (Oral)'		22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered empty.		22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '80'		22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'bpm'	System	22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '18'	(b) (4), (b) (6)	22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'breaths/min'	System	22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '118'	(b) (4), (b) (6)	22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'mmHg'	System	22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:25
User entered '78'	(b) (4), (b) (6)	22 Jan 2021 20:49:40

US3272195

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'mmHg'	System	22 Jan 2021 20:49:40

US3272195

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:49:54

US3272195

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:29
User entered '14 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:49:54

US3272195

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:50:15

US3272195

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:34
User entered '14 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:50:15

US3272195

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:34
User entered 'Urine (URINE)'	(b) (4), (b) (6)	22 Jan 2021 20:50:15

US3272195

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:34
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	22 Jan 2021 20:50:15

US3272195

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:34
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 20:50:15

US3272195

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:34
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 20:50:15

US3272195

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:45:34
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 20:50:15

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered empty.	System	22 Jan 2021 20:50:15

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:50:39

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:28
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 20:50:39

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

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)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:28
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 20:50:39

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'mRNA-1273'	System	22 Jan 2021 20:50:39
DataPoint set to visible.	System	22 Jan 2021 20:47:03

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:28
User entered '14 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:50:39

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:28
User entered '16:56'	(b) (4), (b) (6)	22 Jan 2021 20:50:39

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered '14 Jan 2021 16:56'	System	22 Jan 2021 20:50:39

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:28
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	22 Jan 2021 20:50:39

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:28
User entered 'ONCE'	System	22 Jan 2021 20:50:39

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 20:50:39

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:47:14

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:35
User entered '14 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:47:14

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:35
User entered '15:52'	(b) (4), (b) (6)	22 Jan 2021 20:47:14

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered '14 Jan 2021 15:52'	System	22 Jan 2021 20:47:14

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:23:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:47:26

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:23:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:42
User entered '14 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:47:26

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:23:03

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:42
User entered '15:56'	(b) (4), (b) (6)	22 Jan 2021 20:47:26

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:23:03

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered '14 Jan 2021 15:56'	System	22 Jan 2021 20:47:26

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:47:31

US3272195

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:14:40
User entered 'I'	System	22 Jan 2021 20:47:31

US3272195

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:37:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:47:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:47:48

US3272195

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:37:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:47:02
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 20:47:48

US3272195

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:37:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:47:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Jan 2021 20:47:48

US3272195

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:37:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:47:02
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 20:47:48

US3272195

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:37:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:47:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 20:47:51

US3272195

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:37:49
User entered 'I'	System	22 Jan 2021 20:47:51

US3272195

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:37:49
User entered '1'	System	22 Jan 2021 20:47:51
DataPoint set to visible.	System	22 Jan 2021 20:47:51

US3272195

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:47:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 15:45:08

US3272195

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:47:55
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 15:45:08

US3272195

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:47:55
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Feb 2021 15:45:08

US3272195

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered 'OLD29'	System	17 Feb 2021 15:45:08

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User accepted default value 'Pre-Dose (PREDOSE)'		17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered 'Yes (Y)'		17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '16 Feb 2021'		17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '16:35'		17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered '16 Feb 2021 16:35'	System	17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '37.0' C		17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered 'Oral (Oral)'		17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered empty.		17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '74'		17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered 'bpm'	System	17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '16'		17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered 'breaths/min'	System	17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '120'		17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered 'mmHg'	System	17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '80'		17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered 'mmHg'	System	17 Feb 2021 15:45:49

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User accepted default value 'Post-Dose (POSTDOSE)'		17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered 'Yes (Y)'		17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '16 Feb 2021'		17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '17:34'		17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered '16 Feb 2021 17:34'	System	17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '36.7' C		17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered 'Oral (Oral)'		17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '70'	(b) (4), (b) (6)	17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered 'bpm'	System	17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '14'	(b) (4), (b) (6)	17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered 'breaths/min'	System	17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '123'	(b) (4), (b) (6)	17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered 'mmHg'	System	17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:06
User entered '86'	(b) (4), (b) (6)	17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:23:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered 'mmHg'	System	17 Feb 2021 15:47:44

US3272195

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 15:45:59

US3272195

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:11
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 15:45:59

US3272195

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 15:46:32

US3272195

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:15
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 15:46:32

US3272195

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:15
User entered 'Urine (URINE)'	(b) (4), (b) (6)	17 Feb 2021 15:46:32

US3272195

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:15
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	17 Feb 2021 15:46:32

US3272195

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:15
User entered 'No (N)'	(b) (4), (b) (6)	17 Feb 2021 15:46:32

US3272195

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:15
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 15:46:32

US3272195

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:15
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 15:46:32

US3272195

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:23:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered empty.	System	17 Feb 2021 15:46:32

US3272195

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 15:47:02

US3272195

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:30
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 15:47:02

US3272195

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

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)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:30
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 15:47:02

US3272195

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered 'mRNA-1273'	System	17 Feb 2021 15:47:02
DataPoint set to visible.	System	22 Jan 2021 20:47:51

US3272195

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:30
User entered '16 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 15:47:02

US3272195

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:30
User entered '16:56'	(b) (4), (b) (6)	17 Feb 2021 15:47:02

US3272195

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered '16 Feb 2021 16:56'	System	17 Feb 2021 15:47:02

US3272195

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:30
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	17 Feb 2021 15:47:02

US3272195

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
DataPoint Verified.		15 Apr 2021 20:49:30
User entered 'ONCE'	System	17 Feb 2021 15:47:02

US3272195

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:23:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 15:47:02

US3272195

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:34
User entered 'Yes (Y)'		17 Feb 2021 15:47:54

US3272195

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:43:32
User entered 'I'	System	17 Feb 2021 15:47:54

US3272195

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:11:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:52
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 17:37:21

US3272195

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:11:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:52
User entered '24 Feb 2021'	Ashley Bell (b) (4)	31 Mar 2021 17:37:21

US3272195

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:11:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:52
User entered 'Contact Made (CONTACT MADE)'	Ashley Bell (b) (4)	31 Mar 2021 17:37:21

US3272195

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:23:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:11:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:52
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 17:37:21

US3272195

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:11:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:23:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:49:56
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 17:37:25

US3272195

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:23:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:11:53
User entered 'I'	System	31 Mar 2021 17:37:25

US3272195

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:22
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 17:37:37

US3272195

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:22
User entered '30 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 17:37:37

US3272195

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[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 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:22
User entered 'Clinic (Clinic)'	Ashley Bell (b) (4)	31 Mar 2021 17:37:37

US3272195

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:23:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User entered 'OLD57'	System	31 Mar 2021 17:37:37

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:53
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:53
User entered '30 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:53
User entered '14:39'	Ashley Bell (b) (4)	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User entered '30 Mar 2021 14:39'	System	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:53
User entered '37.1' C	Ashley Bell (b) (4)	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:53
User entered 'Oral (Oral)'	Ashley Bell (b) (4)	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:53
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:53
User entered '77'	Ashley Bell (b) (4)	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User entered 'bpm'	System	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:53
User entered '16'	Ashley Bell (b) (4)	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User entered 'breaths/min'	System	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:53
User entered '127'	Ashley Bell (b) (4)	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User entered 'mmHg'	System	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:53
User entered '88'	Ashley Bell (b) (4)	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User entered 'mmHg'	System	31 Mar 2021 17:38:17

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04

US3272195

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:23:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04

US3272195

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:57
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 17:38:27

US3272195

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:23:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:50:57
User entered '30 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 17:38:27

US3272195

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:01
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 17:38:43

US3272195

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:01
User entered '30 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 17:38:43

US3272195

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:01
User entered '14:43'	Ashley Bell (b) (4)	31 Mar 2021 17:38:43

US3272195

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:23:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:06:04
User entered '30 Mar 2021 14:43'	System	31 Mar 2021 17:38:43

US3272195

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:23:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:00:46
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:59
User entered 'Yes (Y)'	Ashley Bell (b) (4)	07 Nov 2020 00:12:10

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
Reviewed for Safety.		09 Nov 2020 17:06:08
User entered 'USA-US070-2020-mRNA-1273-P301000015'	System	09 Nov 2020 17:05:55
User entered 'New'	(b) (4), (b) (6)	09 Nov 2020 17:05:55

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: As this event is a confirmed diagnosis of Symptomatic COVID-19, please update term to 'COVID-19'.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:07:10
DataPoint Verified.		20 Nov 2020 18:04:28
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)	20 Nov 2020 16:42:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 16:42:34
Data point term sent to Coder	System	20 Nov 2020 14:34:09
Query 'PV Query: As this event is a confirmed diagnosis of Symptomatic COVID-19, please update term to 'COVID-19'.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:33:53
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:33:48
Coding entries removed.	Kayla Flege (b) (4)	20 Nov 2020 14:33:48
User entered 'COVID-19' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:33:48
User opened query 'PV Query: As this event is a confirmed diagnosis of Symptomatic COVID-19, please update term to 'COVID-19'.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:13:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:23:47
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)	10 Nov 2020 20:13:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 20:13:47
Data point term sent to Coder	System	10 Nov 2020 20:12:18
DataPoint Un-verified.	Ashley Bell (b) (4)	10 Nov 2020 20:11:40
Coding entries removed.	Ashley Bell (b) (4)	10 Nov 2020 20:11:40

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Adverse event](#)

Audit	User	Time (GMT)
Signature has been broken.	Ashley Bell (b) (4)	10 Nov 2020 20:11:40
User entered 'COVID 19' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:11:40
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
Data point term sent to Coder	System	07 Nov 2020 20:51:57
User closed query 'For coding purposes, for AE term COVID 19 POSITIVE, please specify if this is COVID 19 test positive, COVID 19 INFECTION or something else. Please update the term with your response.' (Site from System).	System	07 Nov 2020 20:51:44
Query 'For coding purposes, for AE term COVID 19 POSITIVE, please specify if this is COVID 19 test positive, COVID 19 INFECTION or something else. Please update the term with your response.' answered with 'Confirm correct ' (Site from System).	Ashley Bell (b) (4)	07 Nov 2020 20:51:44
User opened query 'For coding purposes, for AE term COVID 19 POSITIVE, please specify if this is COVID 19 test positive, COVID 19 INFECTION or something else. Please update the term with your response.' (Site from System).	Coder Import (b) (4)	07 Nov 2020 18:24:36
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\23.0.	Coder Import (b) (4)	07 Nov 2020 00:14:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Nov 2020 00:14:23
Data point term sent to Coder	System	07 Nov 2020 00:13:17
User entered 'COVID 19 Positive'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered 'Yes (Y)'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered 'Yes (Y)'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered '30 Oct 2020'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Un-verified.	Kayla Flege (b) (4)	11 Dec 2020 16:02:58
Signature has been broken.	Kayla Flege (b) (4)	11 Dec 2020 16:02:58
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 16:02:58
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:07:12
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'ongoing' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:34:03
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:12:29
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:11:42
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:11:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered 'Yes (Y)'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Un-verified.	Kayla Flege (b) (4)	11 Dec 2020 16:02:58
Signature has been broken.	Kayla Flege (b) (4)	11 Dec 2020 16:02:58
User entered '08 Dec 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 16:02:58
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:54:35
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'symptoms still ongoing at this time.' (Site from Safety).	Kayla Flege (b) (4)	01 Dec 2020 20:47:32
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 18:49:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (when symptoms have resolved).	(b) (4), (b) (6)	27 Apr 2021 23:32:08
5. PV Query: Thank you for your response. Please update indication of potassium administered from bradycardia to hypokalemia.		
' canceled (Site from Safety).		
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).	(b) (4), (b) (6)	09 Dec 2020 18:20:36
5. PV Query: Thank you for your response. Please update indication of potassium administered from bradycardia to hypokalemia.		
' (Site from Safety).		
User entered empty.	System	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 20:51:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 20:51:11
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 15:51:53
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'currently still inpatient' (Site from System).	Ashley Bell (b) (4)	11 Nov 2020 18:31:58
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	11 Nov 2020 18:31:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	08 Nov 2020 11:03:08
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Patient is currently ' (Site from System).	Ashley Bell (b) (4)	07 Nov 2020 20:52:09
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	07 Nov 2020 20:51:11
User entered '1' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 20:51:11
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered '07 Nov 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 20:51:11
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:07:15
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'updated' (Site from Safety).	(b) (4)	20 Nov 2020 14:36:18
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:36:12
Signature has been broken.	(b) (4)	20 Nov 2020 14:36:12
User entered '12 Nov 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:36:12
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:12:18
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Un-verified.	Whitney West (b) (4)	01 Dec 2020 21:47:30
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	01 Dec 2020 21:47:30
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
DataPoint Un-verified.	Ashley Bell (b) (4)	11 Nov 2020 18:31:47
Signature has been broken.	Ashley Bell (b) (4)	11 Nov 2020 18:31:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	11 Nov 2020 18:31:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Un-verified.	Whitney West (b) (4)	01 Dec 2020 21:47:30
User entered empty; reason for change New Information	Whitney West (b) (4)	01 Dec 2020 21:47:30
User closed query 'Per CDM: Please update 'Number of Days in ICU' when data becomes available.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:07:48
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
Query 'Per CDM: Please update 'Number of Days in ICU' when data becomes available.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	20 Nov 2020 14:36:22
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:36:12
Signature has been broken.	Kayla Flege (b) (4)	20 Nov 2020 14:36:12
User entered '6' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:36:12
User opened query 'Per CDM: Please update 'Number of Days in ICU' when data becomes available.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 22:15:43
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 15:52:02
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'still inpatient ' (Site from System).	Ashley Bell (b) (4)	11 Nov 2020 18:32:05
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	11 Nov 2020 18:31:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered 'Not Related (NOT RELATED)'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered 'Not Related (NOT RELATED)'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:07:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
Query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:36:27
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:36:12
Signature has been broken.	Kayla Flege (b) (4)	20 Nov 2020 14:36:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:36:12
User opened query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:11:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered 'None (NONE)'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
Signature has been broken.	Whitney West (b) (4)	20 Jan 2021 18:19:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered '0' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:15:31
User entered '1'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered '1' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:15:31
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:50:39
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	11 Dec 2020 16:03:03
DataPoint Un-verified.	Kayla Flege (b) (4)	11 Dec 2020 16:02:58
Signature has been broken.	Kayla Flege (b) (4)	11 Dec 2020 16:02:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 16:02:58
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:20:11
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:54:39
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'symptoms still ongoing' (Site from Safety).	Kayla Flege (b) (4)	01 Dec 2020 20:47:56
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 18:50:13

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:07:20
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'ongoing symptoms' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:36:45
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:13:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: Please provide the radiological evidence of COVID-19, if available. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 20:06:43
Query 'PV Query: Please provide the radiological evidence of COVID-19, if available. ' answered with 'PPD lab report indicated that subject was positive.' (Site from Safety).	Kayla Flege (b) (4)	18 Dec 2020 22:27:29
User opened query 'PV Query: Please provide the radiological evidence of COVID-19, if available. ' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 15:14:51
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 14:48:32
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 14:48:25
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable. ' answered with 'sent fax' (Site from Safety).	Kayla Flege (b) (4)	11 Dec 2020 21:07:22
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' answered with 'Sent fax' (Site from Safety).	Kayla Flege (b) (4)	11 Dec 2020 21:07:01
User closed query 'PV Query: Date of positive COVID-19 test was reported as 02 NOV on COVID diagnostic test form. However, per case narrative subject tested positive on 01 NOV. Please clarify which is correct and update. ' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:51:05

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Date of positive COVID-19 test was reported as 02 NOV on COVID diagnostic test form. However, per case narrative subject tested positive on 01 NOV. Please clarify which is correct and update. ' answered with 'Date of visit to clinic was 02 NOV 2020, got tested 01 NOV 2020 at PCP' (Site from Safety).	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 16:03:48
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 18:21:05
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable. ' (Site from Safety).		09 Dec 2020 18:19:31
User opened query 'PV Query: Date of positive COVID-19 test was reported as 02 NOV on COVID diagnostic test form. However, per case narrative subject tested positive on 01 NOV. Please clarify which is correct and update. ' (Site from Safety).		09 Dec 2020 18:19:01
User closed query 'PV Query: The patient was administered potassium due to bradycardia secondary to COVID-19. Does bradycardia secondary to COVID-19 meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If no, please explain.' (Site from Safety).		02 Dec 2020 13:54:45
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		02 Dec 2020 13:54:43
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' (Site from Safety).		02 Dec 2020 13:54:41

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Discharge summary was sent. ' (Site from Safety). DataPoint Un-verified.	Whitney West (b) (4)	01 Dec 2020 23:35:02
	Whitney West (b) (4)	01 Dec 2020 21:46:38
User entered 'Participant was exposed to coworker with Covid-19 and tested positive 01NOV2020 as did her family members. Oxygen saturations are in the upper 80s and presented to the ED. Diagnosed with acute hypoxic respiratory failure requiring supplemental oxygen up to 3L/NC. Her chest x-ray on 7NOV2020 showed multifocal pneumonia. She was given dexamethasone, azithromycin 500 mg IV q24hour, bronchodilator treatment, acetaminophen, ibuprofen, and remdesevir. Hypokalemia was found incidentally during her hospitalization and she was started on potassium chloride as well.	Whitney West (b) (4)	01 Dec 2020 21:46:38
Participant remained on a non-ICU floor until Discharge on 12NOV2020. Sent home on room air with prescriptions for azithromycin 250 mg tablet-500 mg on day one and then 250 mg tablet on days 2-5, dexamethasone 6 mg once daily x 4 days, and potassium chloride 10 meq BID x 7 days. She was set to follow up with her primary care physician in 3-5 days.' reason for change: Data Entry Error		
Query 'PV Query: The patient was administered potassium due to bradycardia secondary to COVID-19. Does bradycardia secondary to COVID-19 meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If no, please explain.' answered with 'Records have been obtained. Medical diagnosis was hypokalemia. No diagnosis of bradycardia- initial report was based off of patient report. ' (Site from Safety).	Whitney West (b) (4)	01 Dec 2020 21:25:47

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' answered with 'will send in' (Site from Safety).	Kayla Flege (b) (4)	01 Dec 2020 20:50:15
User opened query 'PV Query: The patient was administered potassium due to bradycardia secondary to COVID-19. Does bradycardia secondary to COVID-19 meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If no, please explain.' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 18:51:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' (Site from Safety).		30 Nov 2020 18:50:47
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		30 Nov 2020 18:49:59
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).		23 Nov 2020 20:07:24
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' (Site from Safety).		23 Nov 2020 20:07:23
DataPoint Verified.		23 Nov 2020 20:07:21
		20 Nov 2020 18:04:28

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'obtaining records' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:39:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' answered with 'obtaining records.' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:38:54
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:37:27
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:37:23
Signature has been broken.	Kayla Flege (b) (4)	20 Nov 2020 14:37:23
User entered 'Exposed to coworker. PATIENT WAS ADMITTED TODAY DUE TO WORSENING OF COVID 19. SUBJECT O2 WAS 87 TODAY. PATIENT STATED THEY STARTED HER ON IV ANTIBIOTICS AND SUPPLEMENTAL O2. PATIENT WILL UPDATE THE SITE.' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:37:23
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:13:56
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:13:23
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:12:44

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User signature succeeded.	Adam Brosz (b) (4)	09 Nov 2020 16:22:47
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	07 Nov 2020 20:54:33
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	07 Nov 2020 20:54:33
User entered 'Patient was admitted today due to worsening of COVID 19. Subject O2 was 87 today. Patient stated they started her on IV antibiotics and supplemental O2. Patient will update the site.' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 20:54:33
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	07 Nov 2020 20:51:11
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Nov 2020 20:51:11
User entered '0'	System	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Nov 2020 00:12:50

US3272195

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Dec 2020 21:47:30
User entered '1'	System	11 Nov 2020 18:31:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
Reviewed for Safety.		10 Nov 2020 15:34:30
User entered 'USA-US070-2020-mRNA-1273-P301000015'		10 Nov 2020 15:33:58

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19 pneumonia, LLT: COVID-19 pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	02 Dec 2020 11:10:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Dec 2020 11:10:12
Data point term sent to Coder	System	01 Dec 2020 21:57:06
DataPoint Un-verified.	Whitney West (b) (4)	01 Dec 2020 21:56:24
Coding entries removed.	Whitney West (b) (4)	01 Dec 2020 21:56:24
User entered 'Pneumonia due to COVID-19 virus' reason for change: New Information	Whitney West (b) (4)	01 Dec 2020 21:56:24
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19 pneumonia, LLT: COVID-19 pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 16:57:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 16:57:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
Data point term sent to Coder	System	09 Nov 2020 17:24:31
User entered 'Pneumonia Secondary to Covid 19 positive infection'	Andrea Clement (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Un-verified.	Whitney West (b) (4)	01 Dec 2020 21:56:24
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	01 Dec 2020 21:56:24
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	20 Nov 2020 18:04:28
User closed query 'PV Query Urgent: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).		11 Nov 2020 20:28:48
Query 'PV Query Urgent: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' answered with 'updated' (Site from Safety).	Ashley Bell (b) (4)	10 Nov 2020 20:07:34
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:07:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:42
DataPoint Verified.		10 Nov 2020 18:21:04
User opened query 'PV Query Urgent: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).		09 Nov 2020 19:08:36
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '7 Nov 2020'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 20:56:36
DataPoint Un-verified.	Kayla Flege (b) (4)	01 Dec 2020 20:56:36
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Dec 2020 20:56:36
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Dec 2020 20:55:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Yes (Y)'	Andrea Clement (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 09:10:01
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:54:53
User entered '30 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	01 Dec 2020 21:56:24
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Fixed.' (Site from System).	Whitney West (b) (4)	01 Dec 2020 21:54:39
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 '30NOV2020- participant presented for day 28 convalescent visit. Lungs and breathing effort were returned to baseline, no respiratory symptoms.' (Site from Safety).	Whitney West (b) (4)	01 Dec 2020 21:54:26
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	01 Dec 2020 20:55:44
DataPoint Un-verified.	Kayla Flege (b) (4)	01 Dec 2020 20:55:44
User entered '25 Nov 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	01 Dec 2020 20:55:44
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)	30 Nov 2020 18:51:59
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:40:44
User entered 'Grade 4 (Grade 4)' reason for change:	(b) (4)	
Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:40:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andrea Clement (b) (4)	09 Nov 2020 17:23:47
	(b) (4)	

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 02:00:31
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated patient is in the ICU currently ' (Site from System).	Ashley Bell (b) (4)	10 Nov 2020 20:07:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Nov 2020 17:23:47
User entered 'I'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:39:37
User entered '07 Nov 2020' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 14:39:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '7 Nov 2020'	Andrea Clement (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:19:56
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:39:41
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:39:37
User entered '12 Nov 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:39:37
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:15:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Un-verified.	Whitney West (b) (4)	01 Dec 2020 21:56:24
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	01 Dec 2020 21:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
DataPoint Un-verified.	Ashley Bell (b) (4)	10 Nov 2020 20:07:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:07:26
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Un-verified.	Whitney West (b) (4)	01 Dec 2020 21:56:24
User entered empty; reason for change New Information	Whitney West (b) (4)	01 Dec 2020 21:56:24
User closed query 'Per CDM: Please update 'Number of Days in ICU' when data becomes available.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:22:48
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
Query 'Per CDM: Please update 'Number of Days in ICU' when data becomes available.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	20 Nov 2020 14:39:45
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:39:37
User entered '6' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:39:37
User opened query 'Per CDM: Please update 'Number of Days in ICU' when data becomes available.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 22:20:14
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 02:00:26
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'updated patient is in the ICU currently ' (Site from System).	Ashley Bell (b) (4)	10 Nov 2020 20:07:59
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	10 Nov 2020 20:07:26
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:20:56
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
Query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:39:49
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:39:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:39:37
User opened query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:15:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'None (NONE)'	Andrea Clement (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'I'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:54:58
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'She is recovered. Presented for day 28 convalescent visit on 30NOV2020. Lungs clear to auscultation, breathing without effort, no supplemental O2, no respiratory, pneumonia, or Covid medications, no respiratory symptoms.' (Site from Safety).	Whitney West (b) (4)	01 Dec 2020 21:57:33
DataPoint Un-verified.	Whitney West (b) (4)	01 Dec 2020 21:56:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Whitney West (b) (4)	01 Dec 2020 21:56:24
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 18:52:29
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:20:58
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'ongoing symptoms' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:39:57

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 14:16:15
	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andrea Clement (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:55:00
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' answered with 'Sending readout report with discharge report.' (Site from Safety).	Whitney West (b) (4)	01 Dec 2020 21:58:36
DataPoint Un-verified.	Whitney West (b) (4)	01 Dec 2020 21:56:24
User entered 'SUBJECT ADMITTED TO HOSPITAL ON 07NOV2020 DUE acute respiratory failure due to COVID-19 and pneumonia due to covid-19 virus. Participant was exposed to coworker with Covid-19 and tested positive 01NOV2020 as did her family members. Oxygen saturations are in the upper 80s and presented to the ED. Diagnosed with acute hypoxic respiratory failure requiring supplemental oxygen up to 3L/NC. Her chest x-ray on 7NOV2020 showed multifocal pneumonia- no repeat x-ray. She was given dexamethasone, azithromycin 500 mg IV q24hour, bronchodilator treatment, acetaminophen, ibuprofen, and remdesivir. Participant remained on a non-ICU floor until Discharge on 12NOV2020. Sent home on room air with prescriptions for azithromycin 250 mg tablet- 500 mg on day one and then 250 mg tablet on days 2-5, dexamethasone 6 mg once daily x 4 days, and potassium chloride 10 meq BID x 7 days. She was set to follow up with her primary care physician in 3-5 days. Respiratory symptoms resolved 30NOV2020 with pneumonia resolution.' reason for change: New Information	Whitney West (b) (4)	01 Dec 2020 21:56:24

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 18:52:15
User closed query 'PV Query: Since ICU admission was required for the events of Penumonia secondary to COVID 19 positive infection and Hypoxia, please confirm that severity of these events are Grade 4. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:21:01
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:20:59
Query 'PV Query: Since ICU admission was required for the events of Penumonia secondary to COVID 19 positive infection and Hypoxia, please confirm that severity of these events are Grade 4. If not, please explain.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:41:35
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' answered with 'obtaining records' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:40:09
User opened query 'PV Query: Since ICU admission was required for the events of Penumonia secondary to COVID 19 positive infection and Hypoxia, please confirm that severity of these events are Grade 4. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 23:07:31
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:16:02
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Subject admitted to hospital on 07NOV2020 due to worsening symptoms of Covid 19 positive illness with secondary pneumonia that began being treated in patient 07NOV2020. She was also given supplemental oxygen due to Hypoxia.'	Andrea Clement (b) (4)	09 Nov 2020 17:23:47

PRODUCTION RELEASE (v12.003
EAB) (1725)

2973 of 3760

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 17:23:47

US3272195

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Dec 2020 21:56:24
User entered '1'	System	10 Nov 2020 20:07:26

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
Reviewed for Safety.		10 Nov 2020 15:34:43
User entered 'USA-US070-2020-mRNA-1273-P301000015'		10 Nov 2020 15:34:21

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Conditions associated with abnormal gas exchange, PT: Hypoxia, LLT: Hypoxia - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 17:26:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 17:26:35
Data point term sent to Coder	System	09 Nov 2020 17:25:32
User entered 'Hypoxia'	Andrea Clement (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User closed query 'PV Query Urgent: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:28:53
Query 'PV Query Urgent: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' answered with 'updated' (Site from Safety).	Ashley Bell (b) (4)	10 Nov 2020 20:15:06
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:13:30
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:54
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:25:36
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 18:22:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User opened query 'PV Query Urgent: A case of COVID-19 infection has already been reported; due to this, please update answer to 'No'.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:08:56
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:42:28
User entered '07 Nov 2020' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 14:42:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '7 Nov 2020'	Andrea Clement (b) (4)	09 Nov 2020 17:25:24
	(b) (4)	

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
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). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:21:18
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' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:43:15
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). DataPoint Verified.	(b) (4)	20 Nov 2020 14:43:09
User entered 'Yes (Y)'	Kayla Flege (b) (4)	20 Nov 2020 14:43:09
	(b) (4), (b) (6)	13 Nov 2020 14:17:15
		10 Nov 2020 18:21:04
	Andrea Clement (b) (4)	09 Nov 2020 17:25:24
	(b) (4)	

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
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.' canceled (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 18:54:49
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).		30 Nov 2020 18:53:39
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).		23 Nov 2020 15:22:05
DataPoint Verified.		20 Nov 2020 18:04:28
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	Kayla Flege (b) (4)	20 Nov 2020 14:43:19
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	20 Nov 2020 14:43:09
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:43:09
User entered '12 Nov 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:43:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 02:00:57
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'patient currently in ICU' (Site from System).	Ashley Bell (b) (4)	10 Nov 2020 20:14:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Nov 2020 17:25:24
User entered 'I'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:43:09
User entered '07 Nov 2020' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 14:43:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '7 Nov 2020'	Andrea Clement (b) (4)	09 Nov 2020 17:25:24
	(b) (4)	

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:21:21
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:43:23
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:42:28
User entered '12 Nov 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:42:28
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:17:01
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Un-verified.	Whitney West (b) (4)	01 Dec 2020 21:59:29
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	01 Dec 2020 21:59:29
User closed query 'PV Query: For the event of hypoxia, it was indicated that it was unknown if the subject was admitted to the ICU, however the severity assessment indicated that the subject was admitted to an intensive care. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:21:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
Query 'PV Query: For the event of hypoxia, it was indicated that it was unknown if the subject was admitted to the ICU, however the severity assessment indicated that the subject was admitted to an intensive care. Please reconcile.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:43:27
User opened query 'PV Query: For the event of hypoxia, it was indicated that it was unknown if the subject was admitted to the ICU, however the severity assessment indicated that the subject was admitted to an intensive care. Please reconcile.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:18:07
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	10 Nov 2020 20:13:30
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		10 Nov 2020 20:13:30
DataPoint Un-verified.	Ashley Bell (b) (4)	10 Nov 2020 20:13:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:13:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	09 Nov 2020 17:25:24
User entered 'Unknown (UNK)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 09:07:36
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered with 'Patient report differed from the records.' (Site from System).	Whitney West (b) (4)	01 Dec 2020 22:04:13
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	01 Dec 2020 21:59:29
DataPoint Un-verified.	Whitney West (b) (4)	01 Dec 2020 21:59:29
User entered '0' reason for change: New Information	Whitney West (b) (4)	01 Dec 2020 21:59:29
User closed query 'Per CDM: Please update 'Number of Days in ICU' when data becomes available.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:25:08
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
Query 'Per CDM: Please update 'Number of Days in ICU' when data becomes available.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	20 Nov 2020 14:43:31
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:42:28
User entered '6' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:42:28
User opened query 'Per CDM: Please update 'Number of Days in ICU' when data becomes available.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 22:21:13
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 02:00:59
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'patient currently in ICU' (Site from System).	Ashley Bell (b) (4)	10 Nov 2020 20:14:54

PRODUCTION RELEASE (v12.003
EAB) (1725)

2998 of 3760

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System). DataPoint Verified.	System	10 Nov 2020 20:13:30
	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:25:24
	(b) (4)	

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Not Related (NOT RELATED)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:21:25
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
Query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:43:35
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:42:28
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:42:28
User opened query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:16:50
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'None (NONE)'	Andrea Clement (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:09:59
Query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	23 Nov 2020 18:55:03
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:06:58
User closed query 'Per CDM: Concomitant Medication check box "checked" however concomitant Medication eCRF has not been updated? Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:06:58
Query 'Per CDM: Concomitant Medication check box "checked" however concomitant Medication eCRF has not been updated? Please review and update accordingly.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	20 Nov 2020 14:43:58
User opened query 'Per CDM: Concomitant Medication check box "checked" however concomitant Medication eCRF has not been updated? Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 22:24:56
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'I'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:21:27
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:44:02
DataPoint Un-verified.	Kayla Flege (b) (4)	20 Nov 2020 14:43:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Kayla Flege (b) (4)	20 Nov 2020 14:43:48
Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:17:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andrea Clement (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User entered empty.	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:55:10
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' answered with 'Done. ' (Site from Safety).	Whitney West (b) (4)	01 Dec 2020 22:06:32

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT ADMITTED TO HOSPITAL ON 07NOV2020 DUE TO WORSENING SYMPTOMS OF COVID 19 POSITIVE ILLNESS WITH SECONDARY PNEUMONIA THAT BEGAN BEING TREATED IN PATIENT 07NOV2020. SHE WAS ALSO GIVEN SUPPLEMENTAL OXYGEN DUE TO HYPOXIA. PARTICIPANT WAS EXPOSED TO COWORKER WITH COVID-19 AND TESTED POSITIVE 01NOV2020 AS DID HER FAMILY MEMBERS. OXYGEN SATURATIONS ARE IN THE UPPER 80S AND PRESENTED TO THE ED. DIAGNOSED WITH ACUTE HYPOXIC RESPIRATORY FAILURE REQUIRING SUPPLEMENTAL OXYGEN UP TO 3L/NC. HER CHEST X-RAY ON 7NOV2020 SHOWED MULTIFOCAL PNEUMONIA. SHE WAS GIVEN DEXAMETHASONE, AZITHROMYCIN 500 MG IV Q24HOUR, BRONCHODILATOR TREATMENT, ACETAMINOPHEN, IBUPROFEN, AND REMDESEVIR. HYPOKALEMIA WAS FOUND INCIDENTALLY DURING HER HOSPITALIZATION AND SHE WAS STARTED ON POTASSIUM CHLORIDE AS WELL. PARTICIPANT REMAINED ON A NON-ICU FLOOR UNTIL DISCHARGE ON 12NOV2020. SENT HOME ON ROOM AIR WITH PRESCRIPTIONS FOR AZITHROMYCIN 250 MG TABLET- 500 MG ON DAY ONE AND THEN 250 MG TABLET ON DAYS 2-5, DEXAMETHASONE 6 MG ONCE DAILY X 4 DAYS, AND POTASSIUM CHLORIDE 10 MEQ BID X 7 DAYS. SHE WAS SET TO FOLLOW UP WITH HER PRIMARY CARE PHYSICIAN IN 3-5 DAYS. SHE IS RECOVERED. PRESENTED FOR DAY 28 CONVALESCENT VISIT ON 30NOV2020. LUNGS CLEAR TO AUSCULTATION, BREATHING WITHOUT EFFORT, NO SUPPLEMENTAL O2, NO RESPIRATORY, PNEUMONIA, OR COVID	Whitney West (b) (4) (b) (4)	01 Dec 2020 22:05:48

PRODUCTION RELEASE (v12.003
EAB) (1725)

3012 of 3760

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
MEDICATIONS, NO RESPIRATORY SYMPTOMS.' reason for change: New Information DataPoint Un-verified.	Whitney West (b) (4)	01 Dec 2020 21:59:29
User entered 'SUBJECT ADMITTED TO HOSPITAL ON 07NOV2020 DUE TO WORSENING SYMPTOMS OF COVID 19 POSITIVE ILLNESS WITH SECONDARY PNEUMONIA THAT BEGAN BEING TREATED IN PATIENT 07NOV2020. SHE WAS ALSO GIVEN SUPPLEMENTAL OXYGEN DUE TO HYPOXIA.	Whitney West (b) (4)	01 Dec 2020 21:59:29
She is recovered. Presented for day 28 convalescent visit on 30NOV2020. Lungs clear to auscultation, breathing without effort, no supplemental O2, no respiratory, pneumonia, or Covid medications, no respiratory symptoms.' reason for change: Data Entry Error		
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 18:53:56
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' (Site from Safety).		23 Nov 2020 20:21:29
DataPoint Verified.		20 Nov 2020 18:04:28
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' answered with 'obtaining records' (Site from Safety).	Kayla Flege (b) (4)	20 Nov 2020 14:44:10
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including the radiological evidence of COVID-19). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:17:29

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 20:14:01
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 20:14:01
DataPoint Un-verified.	Ashley Bell (b) (4)	10 Nov 2020 20:14:01
User entered 'SUBJECT ADMITTED TO HOSPITAL ON 07NOV2020 DUE TO WORSENING SYMPTOMS OF COVID 19 POSITIVE ILLNESS WITH SECONDARY PNEUMONIA THAT BEGAN BEING TREATED IN PATIENT 07NOV2020. SHE WAS ALSO GIVEN SUPPLEMENTAL OXYGEN DUE TO HYPOXIA.' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:14:01
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:21:04
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 17:25:24
User entered empty.	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Dec 2020 21:59:29
User entered '1'	System	10 Nov 2020 20:13:30
User entered '0'	System	09 Nov 2020 17:25:24

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Dyspepsia aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:13:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:13:48
Data point term sent to Coder	System	17 Nov 2020 18:02:12
User entered 'worsening acid indigestion'	(b) (4), (b) (6)	17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered 'No (N)'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered 'No (N)'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered 'No (N)'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '16 Nov 2020'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered 'Yes (Y)'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered 'No (N)'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 14:44:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 14:44:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:44:33
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:01:48
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 14:44:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 14:44:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:44:33
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:01:48
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered 'Not Applicable (NOT APPLICABLE)'	Kayla Flege (b) (4)	20 Nov 2020 14:44:33
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

None

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Nov 2020 14:44:33
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	17 Nov 2020 18:01:48
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '1' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:44:33
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 14:44:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 14:44:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Kayla Flege (b) (4)	20 Nov 2020 14:44:33
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:01:48
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:23:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 18:01:48

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Candida infections, PT: Vulvovaginal candidiasis, LLT: Vaginal candidiasis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:03:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 18:03:51
Data point term sent to Coder	System	17 Nov 2020 18:03:16
User entered 'vaginal candidiasis'	(b) (4), (b) (6)	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 14:44:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 14:44:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:44:58
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:02:55
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 14:44:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 14:44:58
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:44:58
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:02:55
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 14:44:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 14:44:58
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:44:58
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:02:55
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '15 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User entered empty.	System	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 22:18:27
User entered 'No (N)' reason for change: Data Entry Error		30 Mar 2021 22:18:27
DataPoint Verified.		20 Nov 2020 18:04:28
User entered 'Yes (Y)'		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	30 Mar 2021 22:18:36
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 22:18:36
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	30 Mar 2021 22:18:27
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 22:18:27
User entered '20 Nov 2021' reason for change: Data Entry Error		30 Mar 2021 22:18:27
DataPoint Verified.		20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User entered empty.	System	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered 'Grade 1/Mild (Grade 1/Mild)'		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered 'No (N)'		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 14:44:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 14:44:58
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:44:58
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:02:55
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 14:44:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 14:44:58
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:44:58
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:02:55
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered 'Not Applicable (NOT APPLICABLE)'	Kayla Flege (b) (4)	20 Nov 2020 14:44:58
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Nov 2020 14:44:58
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	17 Nov 2020 18:02:55
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '1' reason for change: Data Entry Error	Kayla Flege (b) (4)	20 Nov 2020 14:44:58
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 22:18:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		30 Mar 2021 22:18:27
DataPoint Verified.		20 Nov 2020 18:04:28
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 14:45:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 14:45:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	20 Nov 2020 14:45:06
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:02:55
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[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 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:04:28
User entered empty.		17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User entered '0'	System	17 Nov 2020 18:02:55

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05
User entered 'I'	System	20 Nov 2020 14:44:58

US3272195

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:05

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 23:32:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 23:32:54
Data point term sent to Coder	System	01 Dec 2020 23:31:27
User entered 'Hypokalemia'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered 'Yes (Y)'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered '07 Nov 2020'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered empty.	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
User entered empty.	System	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered '20 Nov 2020'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered empty.	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
User entered empty.	System	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered '0'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered '0'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		01 Dec 2020 23:31:40
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		01 Dec 2020 23:31:40
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	01 Dec 2020 23:31:23
User entered '0'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered empty.	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered empty.	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	01 Dec 2020 23:31:40
User entered 'No (N)'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered empty.	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered '0'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered '0'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered '0'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered '0'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User closed query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 19:14:16
Query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken' answered with 'UPDATED MEDICATION LIST' (Site from DM).	Kayla Flege (b) (4)	11 Dec 2020 21:14:19
User opened query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 11:15:49
User entered 'I'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered '0'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4) (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

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 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered empty.	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
DataPoint Verified.		15 Apr 2021 20:51:22
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered 'Hypokalemia was an incidental finding on the participants admission to the hospital for COVID caused hypoxia. The hypokalemia was not symptomatic. The treating physician did not make a determination as to the cause of the hypokalemia. Participant was dismissed from the hospital due to resolution of hypoxia on 12Nov2020. She was given a one week prescription for potassium chloride 10 meq BID x 7 days. The participant finished her prescription on 19NOV2020. Resolved 20NOV2020.'	Whitney West (b) (4)	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
User entered '0'	System	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
User entered 'I'	System	01 Dec 2020 23:31:23

US3272195

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:23:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:42:13
User entered '0'	System	01 Dec 2020 23:31:23

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:23:03

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:00:46
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:26:56
User entered 'Yes (Y)'		20 Aug 2020 00:52:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA D - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 00:55:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 00:55:12
Data point term sent to Coder	System	20 Aug 2020 00:54:25
User entered 'Allegra-D'	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'		20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'seasonal allergies'		20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '120/60' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:13:56
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 120/60 mg, 240/180 mg, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 11:03:54
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 120/60 mg, 240/180 mg, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Nov 2020 00:14:01
User entered 'mg (mg)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:13:56
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 120/60 mg, 240/180 mg, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:57:28
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'as needed (PRN)'	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:45:08
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 00:53:48
User entered 'UN Apr 2016'	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 19:12:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 19:12:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User entered empty.	System	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User entered empty.	System	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:34
User entered empty.	System	20 Aug 2020 00:53:48

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:51:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:51:20
Data point term sent to Coder	System	20 Aug 2020 00:55:26
User entered 'Motrin'	(b) (4), (b) (6)	20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'generalized lumbar backache'		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '800'		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'mg (mg)'		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'as needed (PRN)'		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Oral (ORAL)'		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:45:08
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 00:54:45
User entered 'UN UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'		20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 00:54:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR: Con Med FLONASE was added/changed on 11 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). Query 'Per DM CLR: Con Med FLONASE was added/changed on 11 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'this was not a worsening of condition. subject adds seasonally.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:08:59
User opened query 'Per DM CLR: Con Med FLONASE was added/changed on 11 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 03:06:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:14:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:14:45
Data point term sent to Coder	System	20 Oct 2020 19:14:20
User entered 'FLONASE'	(b) (4), (b) (6)	20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User closed query 'Per DM CLR: Prophylaxis = YES; however there is an ongoing MH condition with this indication (MH#1 SEASONAL ALLERGIES 2007). Please confirm if this is used as Prophylaxis for SEASONAL ALLERGIES. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 11:04:14
Query 'Per DM CLR: Prophylaxis = YES; however there is an ongoing MH condition with this indication (MH#1 SEASONAL ALLERGIES 2007). Please confirm if this is used as Prophylaxis for SEASONAL ALLERGIES. Otherwise, please clarify.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Nov 2020 00:14:21
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:14:17
User opened query 'Per DM CLR: Prophylaxis = YES; however there is an ongoing MH condition with this indication (MH#1 SEASONAL ALLERGIES 2007). Please confirm if this is used as Prophylaxis for SEASONAL ALLERGIES. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:59:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'SEASONAL ALLERGIES'		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'I'		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Other (OTHER)'		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'spray'		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once daily (QD)'		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Nasal (NASAL)'		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
DataPoint Un-verified.		17 Nov 2020 18:07:27
User entered '11 Oct 2020' reason for change: Data Entry Error		17 Nov 2020 18:07:27
DataPoint Verified.		11 Nov 2020 06:09:28
User entered '15 Oct 2020'		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'		20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 19:13:27

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:14:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 19:14:45
Data point term sent to Coder	System	20 Oct 2020 19:14:21
User entered 'influenza vaccine'	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'		20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'influenza'	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '.5'	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'mL (mL)'	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '15 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '15 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User entered empty.	System	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User entered empty.	System	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:48
User entered empty.	System	20 Oct 2020 19:14:12

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 20:26:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 20:26:41
Data point term sent to Coder	System	10 Nov 2020 20:25:54
Coding entries removed.	Ashley Bell (b) (4)	10 Nov 2020 20:25:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 00:17:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 00:17:24
Data point term sent to Coder	System	07 Nov 2020 00:16:17
Coding entries removed.	Ashley Bell (b) (4)	07 Nov 2020 00:16:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 15:08:23

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Nov 2020 15:08:23
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	04 Nov 2020 14:52:07
User entered 'mucinex'	(b) (4), (b) (6)	04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'COVID 19' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:25:43
User entered 'COVID 19 Positive' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:16:10
User entered 'nasal congestion'	(b) (4), (b) (6)	04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:52:34
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR: Please verify this dose as it appear to appear to be a combination dose and only one name was given at the medication name field. If yes, please update to record both active components of this combination medication to match the recorded dosages. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:46:21
Query 'Per DM CLR: Please verify this dose as it appear to appear to be a combination dose and only one name was given at the medication name field. If yes, please update to record both active components of this combination medication to match the recorded dosages. Otherwise, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 15:11:58
User entered '200' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 15:11:33
User opened query 'Per DM CLR: Please verify this dose as it appear to appear to be a combination dose and only one name was given at the medication name field. If yes, please update to record both active components of this combination medication to match the recorded dosages. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:18:17
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 18:23:02
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	18 Dec 2020 22:28:50
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Dec 2020 22:28:44

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1200/200' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Dec 2020 22:28:44
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 03:50:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '2'		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
DataPoint Verified.		15 Apr 2021 20:52:58
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Dec 2020 22:28:44
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Kayla Flege (b) (4)	18 Dec 2020 22:28:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'tablet (TABLET)'		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'as needed (PRN)'		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Oral (ORAL)'		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '30 Oct 2020'		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
DataPoint Verified.		15 Apr 2021 20:53:03
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:09:19
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' answered with 'end date added' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 23:50:42
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 23:50:32
User entered 'No (N)' reason for change: Data Entry Error		17 Feb 2021 23:50:32
User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 03:08:29
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
DataPoint Verified.		15 Apr 2021 20:53:09
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 23:50:32
User entered '08 Dec 2020' reason for change: Data Entry Error		17 Feb 2021 23:50:32
DataPoint Verified.		11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'		04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User entered empty.	System	04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User entered empty.	System	04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:51
User entered empty.	System	04 Nov 2020 14:51:37

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SAMBUCUS NIGRA;ZINC GLUCONATE, PRODUCTSYNONYM: THERA ZINC ELDERBERRY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 07:14:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 07:14:05
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
Data point term sent to Coder	System	10 Nov 2020 20:25:54
Coding entries removed.	Ashley Bell (b) (4)	10 Nov 2020 20:25:51
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SAMBUCUS NIGRA;ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 21:18:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 21:18:36
Data point term sent to Coder	System	07 Nov 2020 00:17:18
Data point term sent to Coder	System	04 Nov 2020 14:53:07
User entered 'elderberry with zinc'	(b) (4), (b) (6)	04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'		04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'COVID 19' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:25:51
User entered 'COVID 19 Positive' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 00:16:25
User entered 'covid symptoms'	(b) (4), (b) (6)	04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 18:23:08
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'subject states there is no dosage on bottle.' (Site from DM).	Kayla Flege (b) (4)	18 Dec 2020 22:30:44
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 03:50:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '2'	(b) (4), (b) (6)	04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'tablet (TABLET)'		04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
DataPoint Un-verified.		17 Nov 2020 18:08:16
User entered 'once daily (QD)' reason for change:		17 Nov 2020 18:08:16
Data Entry Error		
DataPoint Verified.		11 Nov 2020 06:09:28
User entered 'as needed (PRN)'		04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Oral (ORAL)'		04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '30 Oct 2020'		04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'		04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:53:17
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:09:39
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' answered with 'updated end date' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 23:52:02
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 23:51:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 23:51:54
User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 03:08:44
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
DataPoint Verified.		15 Apr 2021 20:53:19
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 23:51:54
User entered '08 Dec 2020' reason for change: Data Entry Error		17 Feb 2021 23:51:54
DataPoint Verified.		11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'		04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User entered '1'	System	17 Nov 2020 18:08:16
User entered empty.	System	04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User entered '1'	System	17 Nov 2020 18:08:16
User entered empty.	System	04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:31:55
User entered '804 (804)'	System	17 Nov 2020 18:08:16
User entered empty.	System	04 Nov 2020 14:52:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
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)	04 Nov 2020 15:10:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 15:10:24
Data point term sent to Coder	System	04 Nov 2020 14:54:10
User entered 'vitamin d'	(b) (4), (b) (6)	04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'nutritional supplement'		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '4000'		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'IU (IU)'		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once daily (QD)'		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Oral (ORAL)'		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '30 Oct 2020'		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'		04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 14:53:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
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)	04 Nov 2020 15:10:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 15:10:25
Data point term sent to Coder	System	04 Nov 2020 14:54:09
User entered 'vitamin c'	(b) (4), (b) (6)	04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'nutritional supplement'		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '846'		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'mg (mg)'		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once daily (QD)'		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Oral (ORAL)'		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '30 Oct 2020'		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.		04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 14:54:05

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 12:28:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 12:28:11
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
Data point term sent to Coder	System	10 Nov 2020 20:19:37
User closed query 'For coding purposes, references indicate different formulations for IV ANTIBOTICS. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	System	10 Nov 2020 20:18:51
Query 'For coding purposes, references indicate different formulations for IV ANTIBOTICS. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' answered with 'updated ' (Site from System).	Ashley Bell (b) (4)	10 Nov 2020 20:18:51
User entered 'ROCEPHIN (ceftriaxone)' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:18:44
Data point term sent to Coder	System	09 Nov 2020 17:28:38
User entered 'Rocephin' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 17:28:32
User opened query 'For coding purposes, references indicate different formulations for IV ANTIBOTICS. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	Coder Import (b) (4)	08 Nov 2020 21:20:35
Data point term sent to Coder	System	07 Nov 2020 21:15:08
User entered 'IV antibiotics'	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Secondary pneumonia due to COVID 19 POSITIVE illness' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 17:28:32
User entered 'COVID 19 Positive'	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '2' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:14:15
User entered 'unk'	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'g (g)' reason for change: Data Entry Error	Andrea Clement (b) (4)	10 Nov 2020 18:14:15
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	09 Nov 2020 17:29:02
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	09 Nov 2020 17:28:32
User entered 'mg (mg)' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 17:28:32
User entered 'Other (OTHER)'	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty; reason for change Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 17:29:02
User entered 'unk'	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once daily (QD)' reason for change:	Andrea Clement (b) (4)	09 Nov 2020 17:28:32
Data Entry Error	(b) (4)	
User entered 'unknown (UNKNOWN)'	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Intravenous (INTRAVENOUS)'	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '07 Nov 2020'	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 17:28:32
User entered empty.	System	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 17:28:32
User entered empty.	System	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 17:28:32
User entered empty.	System	07 Nov 2020 21:14:39

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 04:21:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 04:21:07
Data point term sent to Coder	System	23 Nov 2020 18:55:28
Coding entries removed.	Kayla Flege (b) (4)	23 Nov 2020 18:54:39
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 10:38:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 10:38:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
Data point term sent to Coder	System	10 Nov 2020 20:26:55
Coding entries removed.	Ashley Bell (b) (4)	10 Nov 2020 20:26:06
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 11:19:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 11:19:30
Data point term sent to Coder	System	07 Nov 2020 21:16:09
User entered 'supplemental oxygen'	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
DataPoint Verified.		15 Apr 2021 20:54:03
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User entered 'HYPOXIA' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 18:54:51
DataPoint Un-verified.	Kayla Flege (b) (4)	23 Nov 2020 18:54:39
User entered 'Hypoxeia' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 18:54:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'COVID 19' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:26:06
User entered 'COVID 19 Positive'	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '3' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 17:30:18
User entered 'unk'	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Other (OTHER)'	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Liters' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 17:30:18
User entered 'unknown'	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'other (OTHER)' reason for change: Data Entry Error	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:30:18
User entered 'unknown (UNKNOWN)'	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:51:38
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' answered with 'frequency is correct' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 15:13:33
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:29:55
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'continuous' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 17:30:18
User entered empty.	(b) (4)	
	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '07 Nov 2020'	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
DataPoint Verified.		15 Apr 2021 20:54:12
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 16:09:59
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 23:59:30
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 23:59:25
User entered 'No (N)' reason for change: Data Entry Error		17 Feb 2021 23:59:25
User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 03:09:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
DataPoint Verified.		15 Apr 2021 20:54:15
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Un-verified.	(b) (4), (b) (6)	17 Feb 2021 23:59:25
User entered '20 Nov 2020' reason for change: Data Entry Error		17 Feb 2021 23:59:25
DataPoint Verified.		11 Nov 2020 06:09:28
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User entered empty.	System	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User entered empty.	System	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:23
User entered empty.	System	07 Nov 2020 21:15:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 20:27:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 20:27:47
Data point term sent to Coder	System	10 Nov 2020 20:26:55
Coding entries removed.	Ashley Bell (b) (4)	10 Nov 2020 20:26:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 21:22:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 21:22:20
Data point term sent to Coder	System	07 Nov 2020 21:21:11
User entered 'tylenol'	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'COVID 19' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:26:13
User entered 'COVID 19 Positive'	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '1000'	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'mg (mg)'	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once daily (QD)'	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Oral (ORAL)'	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '02 Nov 2020'	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Nov 2020 21:20:42

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
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)	10 Nov 2020 20:27:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 20:27:46
Data point term sent to Coder	System	10 Nov 2020 20:26:55
Coding entries removed.	Ashley Bell (b) (4)	10 Nov 2020 20:26:20
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)	08 Nov 2020 11:15:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 11:15:30
Data point term sent to Coder	System	07 Nov 2020 21:22:12
User entered 'Melatonin'	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'COVID 19' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:26:20
User entered 'COVID 19 Positive'	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '2'	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'mg (mg)'	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once daily (QD)'	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Oral (ORAL)'	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '02 Nov 2020'	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	07 Nov 2020 21:21:30
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		07 Nov 2020 21:21:30
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		07 Nov 2020 21:21:26
User entered empty.	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Ashley Bell (b) (4)	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Nov 2020 21:21:26

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:54:54
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Nov 2020 10:08:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Nov 2020 10:08:12
Data point term sent to Coder	System	25 Nov 2020 20:59:48
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	25 Nov 2020 20:59:38
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'Updated.' (Site from System).	Whitney West (b) (4)	25 Nov 2020 20:59:38
DataPoint Un-verified.	Whitney West (b) (4)	25 Nov 2020 20:59:27
User entered 'DECADRON (Dexamethasone)' reason for change: Data Entry Error	Whitney West (b) (4)	25 Nov 2020 20:59:27
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	24 Nov 2020 07:55:05
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
Data point term sent to Coder	System	10 Nov 2020 20:26:56
Coding entries removed.	Ashley Bell (b) (4)	10 Nov 2020 20:26:28

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 03:54:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 03:54:41
Data point term sent to Coder	System	09 Nov 2020 17:31:44
User entered 'Decadron'	Andrea Clement (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'COVID 19' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:26:28
User entered 'COVID 19 ILLNESS'	Andrea Clement (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '6'	Andrea Clement (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'mg (mg)'	Andrea Clement (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once daily (QD)'	Andrea Clement (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Oral (ORAL)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '7 Nov 2020'	Andrea Clement (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'	Andrea Clement (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:54:59
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:01:18
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' answered with 'updated stop date' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 15:59:18
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:59:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 15:59:08
User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 03:09:18
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:55:04
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:59:08
User entered '08 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 15:59:08
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:31:21
	(b) (4)	

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4)	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User entered '1'	System	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User entered '1'	System	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:42
User entered '804 (804)'	System	09 Nov 2020 17:31:21

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 03:37:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 03:37:43
Data point term sent to Coder	System	09 Nov 2020 17:33:52
User entered 'AZITHROMYCIN'	Andrea Clement (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'PNEUMONIA SECONDARY TO COVID 19 POSITIVE ILLNESS'	Andrea Clement (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '500'	Andrea Clement (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'mg (mg)'	Andrea Clement (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once daily (QD)'	Andrea Clement (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Intravenous (INTRAVENOUS)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '7 Nov 2020'	Andrea Clement (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
DataPoint Un-verified.	Andrea Clement (b) (4)	12 Nov 2020 17:35:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'	Andrea Clement (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
DataPoint Un-verified.	Andrea Clement (b) (4)	12 Nov 2020 17:35:50
User entered '11 Nov 2020' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:33:22
	(b) (4)	

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4)	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User entered '1'	System	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User entered '1'	System	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:35:55
User entered '804 (804)'	System	09 Nov 2020 17:33:22

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 14:37:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 14:37:58
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
Data point term sent to Coder	System	10 Nov 2020 20:26:55
Data point term sent to Coder	System	09 Nov 2020 17:37:01
Data point term sent to Coder	System	09 Nov 2020 17:35:59
User entered 'REMDESIVIR'	Andrea Clement (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'COVID 19' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:26:48
User entered 'COVID 19 POSITIVE ILLNESS' reason for change: Data Entry Error	Andrea Clement (b) (4)	09 Nov 2020 17:36:21
User entered 'COVID 19 POSITVTE ILLNESS'	Andrea Clement (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '200'	Andrea Clement (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'mg (mg)'	Andrea Clement (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once daily (QD)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Intravenous (INTRAVENOUS)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '7 Nov 2020'	Andrea Clement (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '7 Nov 2020'	Andrea Clement (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4)	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User entered '1'	System	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User entered '1'	System	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:33:52
User entered '804 (804)'	System	09 Nov 2020 17:35:53

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 14:22:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 14:22:59
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
Data point term sent to Coder	System	10 Nov 2020 20:26:56
Data point term sent to Coder	System	09 Nov 2020 17:38:11
User entered 'REMDESIVIR'	Andrea Clement (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'COVID 19' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:26:55
User entered 'COVID 19 POSITIVE ILLNESS'	Andrea Clement (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '100'	Andrea Clement (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'mg (mg)'	Andrea Clement (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once daily (QD)'	Andrea Clement (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Intravenous (INTRAVENOUS)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '8 Nov 2020'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
DataPoint Un-verified.	Andrea Clement (b) (4)	12 Nov 2020 17:37:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 17:37:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'	Andrea Clement (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
DataPoint Un-verified.	Andrea Clement (b) (4)	12 Nov 2020 17:37:02
User entered '11 Nov 2020' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 17:37:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:37:35
	(b) (4)	

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4)	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User entered '1'	System	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User entered '1'	System	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:31
User entered '804 (804)'	System	09 Nov 2020 17:37:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Dec 2020 19:10:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Dec 2020 19:10:28
Data point term sent to Coder	System	24 Dec 2020 19:10:16
Coding entries removed.	Kayla Flege (b) (4)	24 Dec 2020 19:10:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 17:41:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 17:41:35
Data point term sent to Coder	System	09 Nov 2020 17:41:14
User entered 'LOVENOX'	Andrea Clement (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
DataPoint Verified.		15 Apr 2021 20:55:32
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:43:12
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).		10 Mar 2021 15:15:03
DataPoint Un-verified.		10 Mar 2021 15:14:52
User entered 'No (N)' reason for change: Data Entry Error		10 Mar 2021 15:14:52
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).		02 Mar 2021 17:17:58
DataPoint Verified.		11 Nov 2020 06:09:28
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:55:37
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 20:26:30
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	24 Dec 2020 19:10:22
DataPoint Un-verified.	Kayla Flege (b) (4)	24 Dec 2020 19:10:15
User entered 'COVID-19' reason for change: Data Entry Error	Kayla Flege (b) (4)	24 Dec 2020 19:10:15
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 03:51:57
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'DEEP VEIN THROMBOSIS'	Andrea Clement (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '40'	Andrea Clement (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'mg (mg)'	Andrea Clement (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once daily (QD)'	Andrea Clement (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Subcutaneous (SUBCUTANEOUS)'	Andrea Clement (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '7 Nov 2020'	Andrea Clement (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
DataPoint Verified.		15 Apr 2021 20:55:45
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 12:38:42
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'updated end date' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:01:02
DataPoint Un-verified.		19 Feb 2021 16:00:54
User entered 'No (N)' reason for change: Data Entry Error		19 Feb 2021 16:00:54
User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).		05 Feb 2021 08:46:58
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
DataPoint Verified.		15 Apr 2021 20:55:49
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 16:00:54
User entered '08 Dec 2020' reason for change: Data Entry Error		19 Feb 2021 16:00:54
DataPoint Verified.		11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4)	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User entered '1'	System	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User entered '1'	System	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:42
User entered '804 (804)'	System	09 Nov 2020 17:40:50

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: PLASMA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 00:32:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 00:32:41
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
Data point term sent to Coder	System	10 Nov 2020 20:27:56
Coding entries removed.	Ashley Bell (b) (4)	10 Nov 2020 20:27:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: PLASMA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 03:53:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 03:53:41
Data point term sent to Coder	System	09 Nov 2020 18:05:46
User entered 'CONVALESCENT PLASMA'	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'COVID 19' reason for change: Data Entry Error	Ashley Bell (b) (4)	10 Nov 2020 20:27:06
User entered 'COVID 19 POSITIVE ILLNESS'	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'I'	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Other (OTHER)'	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'UNIT (approx 200ML)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'once (ONCE)'	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'Intravenous (INTRAVENOUS)'	Andrea Clement (b) (4) (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered empty.	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '9 Nov 2020'	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '0'	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered '9 Nov 2020'	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 06:09:28
User entered 'No (N)'	Andrea Clement (b) (4)	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User entered empty.	System	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User entered empty.	System	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:34:53
User entered empty.	System	09 Nov 2020 18:05:16

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 20:28:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 20:28:34
Data point term sent to Coder	System	12 Nov 2020 17:39:06
User entered 'Azithromycin'	Andrea Clement (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'Pneumonia Secondary to CoVid 19 illness.'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '500'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'mg (mg)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'once daily (QD)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'Oral (ORAL)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '12 Nov 2020'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 17:38:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 21:14:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 21:14:54
Data point term sent to Coder	System	11 Dec 2020 21:13:38
Coding entries removed.	Kayla Flege (b) (4)	11 Dec 2020 21:12:42
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 08:08:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 08:08:01
Data point term sent to Coder	System	17 Nov 2020 18:12:30
User entered 'Potassium'	(b) (4), (b) (6)	17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'No (N)'		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:56:14
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Un-verified.	Kayla Flege (b) (4)	11 Dec 2020 21:12:42
User entered 'HYPOKALEMIA' reason for change:	(b) (4)	11 Dec 2020 21:12:42
Data Entry Error	Kayla Flege (b) (4)	11 Dec 2020 21:12:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'bradycardia secondary to covid-19'		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '10'		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'Other (OTHER)'		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'meq'		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'twice daily (BID)'		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'Oral (ORAL)'		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '12 Nov 2020'		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '0'		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'Yes (Y)'		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'No (N)'		17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 18:11:35

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 08:05:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 08:05:02
Data point term sent to Coder	System	17 Nov 2020 18:13:30
User entered 'calcium carbonate'	(b) (4), (b) (6)	17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'No (N)'		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'acid indigestion'		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '1000'		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'mg (mg)'		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'as needed (PRN)'		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'Oral (ORAL)'		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'UN UNK 1992'		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '0'		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'Yes (Y)'		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 18:13:11

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 08:08:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 08:08:01
Data point term sent to Coder	System	17 Nov 2020 18:16:35
User entered 'cetirizine'	(b) (4), (b) (6)	17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'No (N)'		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'nasal congestion, allergies - covid 19'		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '10'		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'mg (mg)'		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'as needed (PRN)'		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'Oral (ORAL)'		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '15 Nov 2020'		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '0'		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:01:46
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' answered with 'Continued use of medication for seasonal allergies' (Site from DM).		19 Feb 2021 16:02:09
User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).		29 Jan 2021 03:09:34
DataPoint Verified.		20 Nov 2020 18:05:03
User entered 'Yes (Y)'		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'No (N)'		17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 18:16:06

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 18:20:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 18:20:48
Data point term sent to Coder	System	17 Nov 2020 18:19:37
User entered 'fluconazole'	(b) (4), (b) (6)	17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'No (N)'		17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'vaginal candidiasis'		17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '150'		17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'mg (mg)'		17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
DataPoint Verified.		15 Apr 2021 20:56:37
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 18:37:36
User entered 'once (ONCE)' reason for change: Data Entry Error		09 Apr 2021 18:37:36
DataPoint Verified.		20 Nov 2020 18:05:03
User entered 'other (OTHER)'		17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
DataPoint Verified.		15 Apr 2021 20:56:41
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 18:37:36
User entered empty; reason for change Data Entry Error		09 Apr 2021 18:37:36
DataPoint Verified.		20 Nov 2020 18:05:03
User entered 'once + prn if needed'		17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'Oral (ORAL)'		17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per CDM: Please verify if this pertains to (#5) VAGINAL CANDIDIASIS (start date 15-NOV-2020) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 15:32:13
Query 'Per CDM: Please verify if this pertains to (#5) VAGINAL CANDIDIASIS (start date 15-NOV-2020) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate.' answered with 'STARTED MEDICATION AFTER DAY OF DIAGNOSIS' (Site from DM).	Kayla Flege (b) (4)	11 Dec 2020 16:12:16
User opened query 'Per CDM: Please verify if this pertains to (#5) VAGINAL CANDIDIASIS (start date 15-NOV-2020) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date o the AE? Please review and reconcile Con Med and AE dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 11:43:46
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '0'		17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:19:36
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 18:37:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:37:36
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 10:34:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Nov 2020 18:05:03
		17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:56:51
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 18:37:36
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:37:36
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'No (N)'		17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User entered empty.	System	17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User entered empty.	System	17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:18
User entered empty.	System	17 Nov 2020 18:19:03

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 18:21:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 18:21:48
Data point term sent to Coder	System	17 Nov 2020 18:20:37
User entered 'omeprazole'	(b) (4), (b) (6)	17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'No (N)'		17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'acid indigestion'		17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '20'		17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'mg (mg)'		17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'once daily (QD)'		17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'Oral (ORAL)'		17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.		17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '16 Nov 2020'		17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered '0'		17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:05:03
User entered 'No (N)'		17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 18:19:45

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.		15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 03:34:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 03:34:02
Data point term sent to Coder	System	23 Nov 2020 22:01:11
User entered 'Albuterol Inhaler'	Andrea Clement (b) (4)	23 Nov 2020 22:00:44

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 22:00:44

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User entered 'Covid 19'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 22:00:44

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 20:27:16
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Kayla Flege (b) (4) (b) (4)	24 Dec 2020 19:12:38
User entered '180' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	24 Dec 2020 19:12:27
User entered '80' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	24 Dec 2020 19:11:55
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 03:56:16
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 03:55:52
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 03:55:45
User entered '2'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 22:00:44

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User entered 'Other (OTHER)' reason for change:	Kayla Flege (b) (4)	24 Dec 2020 19:11:55
Data Entry Error	(b) (4)	
User entered 'puff (PUFF)'	Andrea Clement (b) (4)	23 Nov 2020 22:00:44
	(b) (4)	

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User entered 'mcg' reason for change: Data Entry Error	Kayla Flege (b) (4)	24 Dec 2020 19:11:55
User entered empty.	Andrea Clement (b) (4)	23 Nov 2020 22:00:44

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User entered 'three times daily (TID)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 22:00:44

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.		15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User entered empty.	Andrea Clement (b) (4)	23 Nov 2020 22:00:44
	(b) (4)	

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.		15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 22:00:44

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.		15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User entered empty.	Andrea Clement (b) (4)	23 Nov 2020 22:00:44
	(b) (4)	

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.		15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User entered '18 Nov 2020'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 22:00:44

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.		15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User entered '0'	Andrea Clement (b) (4)	23 Nov 2020 22:00:44
	(b) (4)	

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:02:07
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' answered with 'updated' (Site from DM)	(b) (4), (b) (6)	19 Feb 2021 16:03:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 16:03:02
User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 03:10:05
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 22:00:44

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.		15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	19 Feb 2021 16:03:02
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	19 Feb 2021 16:02:53
User entered '08 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 16:02:53
User entered empty.	Andrea Clement (b) (4)	23 Nov 2020 22:00:44
	(b) (4)	

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
DataPoint Verified.		15 Apr 2021 20:57:57
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:02:50
User entered 'No (N)'	Andrea Clement (b) (4)	23 Nov 2020 22:00:44
	(b) (4)	

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
User entered '3'	System	23 Nov 2020 22:00:44

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
User entered '1'	System	23 Nov 2020 22:00:44

US3272195

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:23:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 07:36:23
User entered '804 (804)'	System	23 Nov 2020 22:00:44

US3272195

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:23:03

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:00:46
DataPoint Verified.		15 Apr 2021 20:58:28
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:41
User entered 'Yes (Y)'	Whitney West (b) (4)	01 Dec 2020 23:47:07

US3272195

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:23:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:58:37
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered '07 Nov 2020'	Whitney West (b) (4)	01 Dec 2020 23:49:39

US3272195

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:23:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:58:37
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered 'Chest x-ray'	Whitney West (b) (4)	01 Dec 2020 23:49:39

US3272195

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:23:03

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:58:37
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:53:23
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:56:46
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	01 Dec 2020 23:49:39

US3272195

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:23:03

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:58:37
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:02:37
User entered empty.	Whitney West (b) (4)	01 Dec 2020 23:49:39

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'USA-US070-2020-MRNA-1273-P301000015'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Adam'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Brosz'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered '2444 W. Faidley Ave'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Grand Island'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'NE'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered '68803'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		10 Nov 2020 15:37:08
User entered 'US'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	21 Dec 2020 20:07:14
User entered '8'	System	14 Dec 2020 16:01:14
User entered '7'	System	11 Dec 2020 18:52:47
User entered '6'	System	02 Dec 2020 13:55:27
User entered '5'	System	23 Nov 2020 20:22:36
User entered '4'	System	13 Nov 2020 20:19:16
User entered '3'	System	11 Nov 2020 20:29:27
User entered '2'	System	10 Nov 2020 15:37:23
User entered '1'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'USA-US070-2020-MRNA-1273-P301000015'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Adam'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Brosz'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered '2444 W. Faidley Ave'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Grand Island'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'NE'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered '68803'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:37:08
User entered 'US'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	21 Dec 2020 20:07:14
User entered '8'	System	14 Dec 2020 16:01:14
User entered '7'	System	11 Dec 2020 18:52:47
User entered '6'	System	02 Dec 2020 13:55:27
User entered '5'	System	23 Nov 2020 20:22:36
User entered '4'	System	13 Nov 2020 20:19:16
User entered '3'	System	11 Nov 2020 20:29:27
User entered '2'	System	10 Nov 2020 15:37:23
User entered '1'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:23:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
User entered '09/Nov/2020 17:06'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:23:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		10 Nov 2020 15:37:08
User entered 'I'		09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'USA-US070-2020-MRNA-1273-P301000015'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Adam'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Brosz'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered '2444 W. Faidley Ave'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Grand Island'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'NE'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered '68803'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:37:08
User entered 'US'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	21 Dec 2020 20:07:14
User entered '8'	System	14 Dec 2020 16:01:14
User entered '7'	System	11 Dec 2020 18:52:47
User entered '6'	System	02 Dec 2020 13:55:27
User entered '5'	System	23 Nov 2020 20:22:36
User entered '4'	System	13 Nov 2020 20:19:16
User entered '3'	System	11 Nov 2020 20:29:27
User entered '2'	System	10 Nov 2020 15:37:23
User entered '1'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:23:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
User entered '10/Nov/2020 15:37'	System	10 Nov 2020 15:37:23

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:23:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:29:13
DataPoint Verified.		10 Nov 2020 18:19:50
User entered 'I'		10 Nov 2020 15:37:23

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'USA-US070-2020-MRNA-1273-P301000015'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Adam'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Brosz'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered '2444 W. Faidley Ave'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Grand Island'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'NE'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered '68803'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		10 Nov 2020 15:37:08
User entered 'US'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	21 Dec 2020 20:07:14
User entered '8'	System	14 Dec 2020 16:01:14
User entered '7'	System	11 Dec 2020 18:52:47
User entered '6'	System	02 Dec 2020 13:55:27
User entered '5'	System	23 Nov 2020 20:22:36
User entered '4'	System	13 Nov 2020 20:19:16
User entered '3'	System	11 Nov 2020 20:29:27
User entered '2'	System	10 Nov 2020 15:37:23
User entered '1'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:23:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:54
User entered '11/Nov/2020 20:29'	System	11 Nov 2020 20:29:27

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:23:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:54
Reviewed for Safety.		13 Nov 2020 20:18:51
User entered 'I'		11 Nov 2020 20:29:27

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'USA-US070-2020-MRNA-1273-P301000015'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Adam'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Brosz'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered '2444 W. Faidley Ave'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Grand Island'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'NE'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered '68803'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:37:08
User entered 'US'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	21 Dec 2020 20:07:14
User entered '8'	System	14 Dec 2020 16:01:14
User entered '7'	System	11 Dec 2020 18:52:47
User entered '6'	System	02 Dec 2020 13:55:27
User entered '5'	System	23 Nov 2020 20:22:36
User entered '4'	System	13 Nov 2020 20:19:16
User entered '3'	System	11 Nov 2020 20:29:27
User entered '2'	System	10 Nov 2020 15:37:23
User entered '1'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:23:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:54
User entered '13/Nov/2020 20:19'	System	13 Nov 2020 20:19:16

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:23:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:54
Reviewed for Safety.		23 Nov 2020 20:22:27
User entered 'I'		13 Nov 2020 20:19:16

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'USA-US070-2020-MRNA-1273-P301000015'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Adam'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Brosz'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered '2444 W. Faidley Ave'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Grand Island'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'NE'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered '68803'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:37:08
User entered 'US'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	21 Dec 2020 20:07:14
User entered '8'	System	14 Dec 2020 16:01:14
User entered '7'	System	11 Dec 2020 18:52:47
User entered '6'	System	02 Dec 2020 13:55:27
User entered '5'	System	23 Nov 2020 20:22:36
User entered '4'	System	13 Nov 2020 20:19:16
User entered '3'	System	11 Nov 2020 20:29:27
User entered '2'	System	10 Nov 2020 15:37:23
User entered '1'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:23:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:50:54
User entered '23/Nov/2020 15:22'	System	23 Nov 2020 20:22:36

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:23:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:55:16
DataPoint Verified.		23 Nov 2020 21:50:54
User entered 'I'		23 Nov 2020 20:22:36

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'USA-US070-2020-MRNA-1273-P301000015'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Adam'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Brosz'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered '2444 W. Faidley Ave'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Grand Island'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'NE'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered '68803'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		10 Nov 2020 15:37:08
User entered 'US'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	21 Dec 2020 20:07:14
User entered '8'	System	14 Dec 2020 16:01:14
User entered '7'	System	11 Dec 2020 18:52:47
User entered '6'	System	02 Dec 2020 13:55:27
User entered '5'	System	23 Nov 2020 20:22:36
User entered '4'	System	13 Nov 2020 20:19:16
User entered '3'	System	11 Nov 2020 20:29:27
User entered '2'	System	10 Nov 2020 15:37:23
User entered '1'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:23:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:12
User entered '02/Dec/2020 13:55'	System	02 Dec 2020 13:55:27

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:23:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:12
Reviewed for Safety.		11 Dec 2020 18:52:32
User entered 'I'		02 Dec 2020 13:55:27

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'USA-US070-2020-MRNA-1273-P301000015'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Adam'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Brosz'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered '2444 W. Faidley Ave'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Grand Island'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'NE'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered '68803'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		10 Nov 2020 15:37:08
User entered 'US'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	21 Dec 2020 20:07:14
User entered '8'	System	14 Dec 2020 16:01:14
User entered '7'	System	11 Dec 2020 18:52:47
User entered '6'	System	02 Dec 2020 13:55:27
User entered '5'	System	23 Nov 2020 20:22:36
User entered '4'	System	13 Nov 2020 20:19:16
User entered '3'	System	11 Nov 2020 20:29:27
User entered '2'	System	10 Nov 2020 15:37:23
User entered '1'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:23:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:12
User entered '11/Dec/2020 13:52'	System	11 Dec 2020 18:52:47

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:23:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:12
Reviewed for Safety.		14 Dec 2020 16:00:57
User entered '1'		11 Dec 2020 18:52:47

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'USA-US070-2020-MRNA-1273-P301000015'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 17:06:25
User entered 'Adam'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Brosz'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered '2444 W. Faidley Ave'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Grand Island'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'NE'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered '68803'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		10 Nov 2020 15:37:08
User entered 'US'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	21 Dec 2020 20:07:14
User entered '8'	System	14 Dec 2020 16:01:14
User entered '7'	System	11 Dec 2020 18:52:47
User entered '6'	System	02 Dec 2020 13:55:27
User entered '5'	System	23 Nov 2020 20:22:36
User entered '4'	System	13 Nov 2020 20:19:16
User entered '3'	System	11 Nov 2020 20:29:27
User entered '2'	System	10 Nov 2020 15:37:23
User entered '1'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:23:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:12
User entered '14/Dec/2020 11:01'	System	14 Dec 2020 16:01:14

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:23:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:12
Reviewed for Safety.		21 Dec 2020 20:07:18
User entered 'I'		14 Dec 2020 16:01:14

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'USA-US070-2020-MRNA-1273-P301000015'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Yes (Y)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'No (N)'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Adam'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Brosz'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered '2444 W. Faidley Ave'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'Grand Island'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered 'NE'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		09 Nov 2020 17:06:25
User entered '68803'	System	09 Nov 2020 17:05:55

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:19:50
Reviewed for Safety.		10 Nov 2020 15:37:08
User entered 'US'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:23:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	21 Dec 2020 20:07:14
User entered '8'	System	14 Dec 2020 16:01:14
User entered '7'	System	11 Dec 2020 18:52:47
User entered '6'	System	02 Dec 2020 13:55:27
User entered '5'	System	23 Nov 2020 20:22:36
User entered '4'	System	13 Nov 2020 20:19:16
User entered '3'	System	11 Nov 2020 20:29:27
User entered '2'	System	10 Nov 2020 15:37:23
User entered '1'	System	09 Nov 2020 17:06:34

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:23:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:12
User entered '21/Dec/2020 15:07'	System	21 Dec 2020 20:07:14

US3272195

Folder: SAE USA-US070-2020-MRNA-1273-P301000015

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:23:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 22:22:53
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:51:12
Reviewed for Safety.		21 Dec 2020 20:07:18
User entered 'I'		21 Dec 2020 20:07:14