

US3452295 (Prod: Lynn Health Science Institute)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:47:54

All time stamps listed in this document are displayed in GMT

US3452295

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

[Participant ID](#)

US3452295

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

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Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	62
Age Units	YEARS
Age (Derived)	63
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 18:16:19

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Date of Informed Consent (<i>dd MMM yyyy</i>)	06 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 18:16:19

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 18:16:19

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 18:16:19

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Condition	LOW TESTOSTERONE
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)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Condition	HIGH BLOOD PRESSURE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Condition	SINUS SURGERY
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Condition	ALLERGY TO SULFA
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Condition	ALLERGY TO SACCHARIN
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 18:16:19

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Condition	CHRONIC SINUSITIS
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Start Year (derived)	1977
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	16:32 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:32
Height (xxx.x)	71 in
Weight (xxx.x)	254.8 lb
BMI (xxx.x)	35.61169 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 18:16:19

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 18:16:19

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 18:16:19

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 101810

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 18:16:19

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

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)	06 AUG 2020
Time of assessment (00:00-23:59)	16:32 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 16:32
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Height	ND - Not Done
Weight	ND - Not Done
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)	06 AUG 2020
Time of assessment (00:00-23:59)	17:26 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 17:26
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

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) 06 AUG 2020

What was the treatment time? (00:00-23:59) 16:46 (24 HR)

Treatment Date and Time (derived) 06 AUG 2020 16:46

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 AUG 2020

Collection time (00:00-23:59)

16:40 (24 HR)

Collection date and time (derived)

06 AUG 2020 16:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Collection date (dd MMM yyyy)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:37	06 AUG 2020 16:37
Nasopharyngeal Swab 2	Yes	16:37	06 AUG 2020 16:37

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

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

98.2 °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

06 AUG 2020 17:22

PC Open Date & Time

06 AUG 2020 17:06

PC Close Date & Time

06 AUG 2020 19:36

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	06 AUG 2020 20:31
PC Open Date & Time	06 AUG 2020 20:31
PC Close Date & Time	07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	07 AUG 2020 18:45
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:47:54

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

100.5 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 AUG 2020 00:35

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 AUG 2020 21:58

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	10 AUG 2020 17:40
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	11 AUG 2020 23:57
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	13 AUG 2020 04:04
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 21:31

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

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

06 AUG 2020 17:23

PC Open Date & Time

06 AUG 2020 17:06

PC Close Date & Time

06 AUG 2020 19:36

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

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

06 AUG 2020 20:32

PC Open Date & Time

06 AUG 2020 20:31

PC Close Date & Time

07 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:47:54

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 18:48

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:47:54

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

09 AUG 2020 00:36

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 21:58

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 17:41

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 23:57

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:47:54

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

13 AUG 2020 04:04

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

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 ☐

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 17:23
PC Open Date & Time	06 AUG 2020 17:06
PC Close Date & Time	06 AUG 2020 19:36

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

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 ☐

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 20:32
PC Open Date & Time	06 AUG 2020 20:31
PC Close Date & Time	07 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

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 ☒

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 18:49
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 00:36
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

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 ☒

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 17:41
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

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 ☒

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 23:58
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

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 ☒

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US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 04:05
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3452295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 AUG 2020 21:31
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3452295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

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

ND PATIENT MOVED TO
CONVALESCENT PERIOD

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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

ND PATIENT MOVED TO
CONVALESCENT PERIOD

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

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

ND PATIENT MOVED TO
CONVALESCENT PERIOD

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

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)	10 SEP 2020
Time of assessment (00:00-23:59)	11:39 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:39
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3452295

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3452295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

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

Collection date (dd MMM yyyy)	10 SEP 2020
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Collection time (00:00-23:59)	11:41 (24 HR)
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Collection date and time (derived)	10 SEP 2020 11:41
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US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:43	10 SEP 2020 11:43
Nasopharyngeal Swab 2	No		

US3452295

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

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) _____

US3452295

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3452295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 OCT 2020

Collection time (00:00-23:59)

11:25 (24 HR)

Collection date and time (derived)

2 OCT 2020 11:25

US3452295

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 18:16:19

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 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"/>

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 OCT 2020 12:01:10

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 03:50:03

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 05:15:18

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 NOV 2020 12:01:50
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 05:54:09

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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	24 NOV 2020 03:39:44
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 NOV 2020 01:17:26
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 04:51:01
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

12 DEC 2020 12:42:07

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 173

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

23 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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	15 MAR 2021 12:33:02
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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	23 MAR 2021 20:57:39
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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	27 MAR 2021 00:02:30
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

04 APR 2021 12:10:07

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 02:43:27
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

17 APR 2021 00:04:20

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 12:04:03

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Patient Cloud Open Date & Time	14 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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°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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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="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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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="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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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12 MAR 2022 00:01

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16 MAR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

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23 MAR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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30 MAR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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02 APR 2022 00:01

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06 APR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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13 APR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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16 APR 2022 00:01

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20 APR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

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27 APR 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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30 APR 2022 00:01

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04 MAY 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

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11 MAY 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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18 MAY 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

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Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

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25 MAY 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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="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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 ☐

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 <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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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°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"/>

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3452295

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:47:54

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		11 MAR 2021 02:53:39

US3452295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 21:44:59

Generated On: 11 Aug 2021 22:47:54

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

Visit date (dd MMM yyyy)	09 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 21:44:59

Generated On: 11 Aug 2021 22:47:54

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) _____

US3452295

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 21:44:59

Generated On: 11 Aug 2021 22:47:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3452295

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 21:44:59

Generated On: 11 Aug 2021 22:47:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 MAR 2021
Collection time (00:00-23:59)	12:04 (24 HR)
Collection date and time (derived)	09 MAR 2021 12:04

US3452295

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 21:44:59

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Date of Contact	10 AUG 2020
Time of Contact	12:15
Date and Time of Contact (derived)	10 AUG 2020 12:15
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 21:44:56

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 21:44:56

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Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Form: Symptom Log (6)

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

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

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 21:44:56

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

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Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 21:44:56

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Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 21:44:56

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

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Form: Symptom Log (8)

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Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
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"/>

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

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Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 21:44:56

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 21:44:56

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Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Form: Symptom Log (9)

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

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Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 21:44:56

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Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020
------	-------------

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

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

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020
------	-------------

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

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

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 21:44:56

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020
------	-------------

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020
------	-------------

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

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

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

Temperature	98.1 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020
------	-------------

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

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

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

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

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

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Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (19)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Form: Symptom Log (19)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (19)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Form: Symptom Log (20)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

Date	29 AUG 2020
------	-------------

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020
------	-------------

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Symptom Day

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020
------	-------------

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

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

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

Temperature	98.2 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 SEP 2020
------	-------------

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

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

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 SEP 2020
------	-------------

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

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

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

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

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 SEP 2020
------	-------------

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

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

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

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

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Date of Visit	10 AUG 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	10 AUG 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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____ 16 /minute

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____ 95 BPM

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____ 95 %

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 _____

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 AUG 2020
Day 5	Yes	14 AUG 2020
Day 7	Yes	16 AUG 2020
Day 9	Yes	18 AUG 2020
Day 14	Yes	23 AUG 2020
Day 21	Yes	30 AUG 2020
Day 28	Yes	08 SEP 2020

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	SICKD1

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 12:23
Height (xxx.x)	71 in
Weight (xxx.x)	254.7 lb
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

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Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 AUG 2020

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	SICKD28

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:35
Height (xxx.x)	71.0 in
Weight (xxx.x)	253.9 lb
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3452295

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

08 SEP 2020

US3452295

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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

Visit date (dd MMM yyyy)	11 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3452295

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 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>)	11 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

US3452295

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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

US3452295

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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)	11 JAN 2021
Time of assessment (00:00-23:59)	14:04 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 14:04
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3452295

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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)	11 JAN 2021
Time of assessment (00:00-23:59)	14:55 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 14:55
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3452295

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

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3452295

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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) 11 JAN 2021

What was the treatment time? (00:00-23:59) 14:25 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 14:25

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

What was the frequency of the study treatment dosing? ONCE

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

US3452295

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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

Collection date (dd MMM yyyy)	11 JAN 2021
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Collection time (00:00-23:59)	14:07 (24 HR)
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Collection date and time (derived)	11 JAN 2021 14:07
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US3452295

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	14:06
Collection Date and Time (derived)	11 JAN 2021 14:06

US3452295

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

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 21:44:59

Generated On: 11 Aug 2021 22:47:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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)	08 FEB 2021
Time of assessment (00:00-23:59)	12:16 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 12:16
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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)	08 FEB 2021
Time of assessment (00:00-23:59)	13:01 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 13:01
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3452295

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 FEB 2021

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

US3452295

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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) 08 FEB 2021

What was the treatment time? (00:00-23:59) 12:31 (24 HR)

Treatment Date and Time (derived) 08 FEB 2021 12:31

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

US3452295

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3452295

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3452295

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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) _____

US3452295

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3452295

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

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

Collection date (dd MMM yyyy)	09 MAR 2021
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Collection time (00:00-23:59)	12:04 (24 HR)
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Collection date and time (derived)	09 MAR 2021 12:04
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US3452295

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 17:20:52

Generated On: 11 Aug 2021 22:47:54

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 17:20:52

Generated On: 11 Aug 2021 22:47:54

AEID

Adverse event

WORSENING OF ACID REFLUX

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 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 AUG 2020

End time (00:00-23:59)

08:00 (24 HR)

AE End Date and Time (derived)

13 AUG 2020 08:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 17:20:52

Generated On: 11 Aug 2021 22:47:54

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

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 17:20:52

Generated On: 11 Aug 2021 22:47:54

AEID	USA-US208-2020-MRNA-1273-P30 1000001
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)	06 AUG 2020
Start time (00:00-23:59)	16:40 (24 HR)
AE start date and time (derived)	06 AUG 2020 16:40
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 17:20:52

Generated On: 11 Aug 2021 22:47:54

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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 checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 17:20:52

Generated On: 11 Aug 2021 22:47:54

PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. HE RETURNED WITHIN 72 HOURS FOR ILLNESS VISIT. SYMPTOMS AND CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. PATIENT TESTED POSITIVE AT SCREENING DATE 06-AUG-2020 AND RESULTS WERE RECEIVED 13-AUG-2020 AND AGAIN ON 10-AUG-2020. NO FURTHER TESTING HAS BEEN DONE. POSITIVE RESULT CONFIRMED ON 17-AUG-2020. 1ST VACCINE WAS RECEIVED ON 06-AUG-2020 HOWEVER THE 2ND VACCINE WILL NOT BE GIVEN

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

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

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

Yes ☒

No ☐

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

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HIGH BLOOD PRESSURE

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

	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 2015	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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Name of Medication PRILOSEC

Prophylaxis Yes ☐
No ☒

Indication HEARTBURN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

	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 2015	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

Name of Medication CERTIRIZINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

	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 2015	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

Name of Medication PEPCID

Prophylaxis Yes ☐
No ☒

Indication STOMACH COATING/ACID
REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 03:16:50

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 AUG 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SINUS CONGESTION/ COVID 19

Dose per administration 1

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

If dose unit is Other, specify SQUIRT

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 AUG 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

Name of Medication ZICAM (ZINC ACETATE AND
ZINC GLUCONATE)

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

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	07 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 AUG 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

Name of Medication BENZONATE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 03:16:50

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	03 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

Name of Medication ALBUTEROL PRO AIR

Prophylaxis Yes ☐
No ☒

Indication CHEST CONGESTION/ COVID 19

Dose per administration 32

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 13 SEP 2020		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 03:16:50

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Name of Medication OMEGA 3 ACID
(ALPHA-LINOLENIC ACID,
EICOSAPENTAENOIC ACID,
AND DOCOSAHEXAENOIC ACID
)

Prophylaxis Yes ☒
No ☐

Indication IMMUNE HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 03:16:50

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	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 AUG 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication IMMUNE BOOST

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 AUG 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 AUG 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 03:16:50

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Name of Medication AUGMENTIN/CLAVULANIC
ACID

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF CHRONIC
SINUSITIS

Dose per administration 825/125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 03:16:50

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	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)	03 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

Name of Medication AUGMENTIN/CLAVULANIC
ACID

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF SINUSITIS

Dose per administration 875/125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 03:16:50

Generated On: 11 Aug 2021 22:47:54

	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)	02 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)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3452295

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 21:44:56

Generated On: 11 Aug 2021 22:47:54

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3452295

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

Date of dosing discontinuation (dd MMM yyyy) 10 AUG 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3452295

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:47:54

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 ☐

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

SAEID	USA-US208-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

SAEID	USA-US208-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/AUG/2020 09:40
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

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

SAEID	USA-US208-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	28/AUG/2020 11:40
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

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 21:44:58

Generated On: 11 Aug 2021 22:47:54

SAEID	USA-US208-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/SEP/2020 22:07
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

US3452295 (Prod: Lynn Health Science Institute)

US3452295

Form: Participant Creation

Generated On: 11 Aug 2021 22:47:54

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'US3452295'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:14:10

US3452295

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:20:09

US3452295

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:14:11

US3452295

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Clinic (Clinic)'	(b) (4) Kim Calloway (b) (4) (b) (4)	06 Aug 2020 21:20:09

US3452295

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'SCRN'	System	06 Aug 2020 21:20:09

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered (b) (6) 1957'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:14:12

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '62'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'YEARS'	System	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '63'	System	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Male (M)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'I'	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 23:45:54
	(b) (4)	

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 23:45:54
	(b) (4)	

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 23:45:54
	(b) (4)	

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:45:54

US3452295

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:47:54

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:45:54
	(b) (4)	

US3452295

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:54

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '06 Aug 2020'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:20:30
	(b) (4)	

US3452295

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'Aug 2020'	System	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '2020'	System	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:54

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Amendment 1 (1)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:20:30

US3452295

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 21:20:30
	(b) (4)	

US3452295

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:54

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 21:20:30
	(b) (4)	

US3452295

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 21:20:30
	(b) (4)	

US3452295

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 21:20:30
	(b) (4)	

US3452295

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:14:11

US3452295

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:47:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'I'	System	06 Aug 2020 21:20:36

US3452295

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:20:36

US3452295

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:47:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:46:09
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
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)	06 Aug 2020 23:48:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:48:00
Data point term sent to Coder	System	06 Aug 2020 23:46:55
User entered 'SEASONAL ALLERGIES'	Kim Calloway (b) (4)	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'UN UNK 2015'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:46:26
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:46:26
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'Jan 2015'	System	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '2015'	System	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Aug 2020 23:46:26

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:48:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:48:00
Data point term sent to Coder	System	06 Aug 2020 23:46:55
User entered 'HEARTBURN'	Kim Calloway (b) (4)	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'UN UNK 2010'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:46:44
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:46:44
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'Jan 2010'	System	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '2010'	System	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Aug 2020 23:46:44

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User coded data point as SOC: Investigations, HLGHT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:49:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:49:01
Data point term sent to Coder	System	06 Aug 2020 23:47:55
User entered 'LOW TESTOSTERONE'	Kim Calloway (b) (4)	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'UN UNK 2017'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:11
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:11
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'Jan 2017'	System	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '2017'	System	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Aug 2020 23:47:11

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Aug 2020 23:49:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 23:49:01
Data point term sent to Coder	System	06 Aug 2020 23:47:55
User entered 'HIGH BLOOD PRESSURE'	Kim Calloway (b) (4) (b) (4)	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'UN UNK 2015'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'Jan 2015'	System	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '2015'	System	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Aug 2020 23:47:32

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:47:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:49:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:49:01
Data point term sent to Coder	System	06 Aug 2020 23:47:56
User entered 'SINUS SURGERY'	Kim Calloway (b) (4)	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'UN UNK 1995'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:47:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:50
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:47:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'UN UNK 1995'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:47:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'Jan 1995'	System	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '1995'	System	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'Jan 1995'	System	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '1995'	System	06 Aug 2020 23:47:50

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:47:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:50:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:50:02
Data point term sent to Coder	System	06 Aug 2020 23:48:57
User entered 'ALLERGY TO SULFA'	Kim Calloway (b) (4)	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'UN UNK 1995'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:47:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:47:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 23:48:05
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:47:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'Jan 1995'	System	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '1995'	System	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Aug 2020 23:48:05

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:47:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Reaction to food additive, LLT: Artificial sweetener intolerance - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:53:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 23:53:04
Data point term sent to Coder	System	06 Aug 2020 23:48:56
User entered 'ALLERGY TO SACCHARIN'	Kim Calloway (b) (4)	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'UN UNK 1975'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:47:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:47:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:31
	(b) (4)	

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:47:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:47:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'Jan 1975'	System	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '1975'	System	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Aug 2020 23:48:31

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:47:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:32:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:32:19
Data point term sent to Coder	System	06 Oct 2020 16:31:10
User entered 'chronic sinusitis'	(b) (4), (b) (6)	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'un UNK 1977'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:47:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:47:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:47:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'Jan 1977'	System	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '1977'	System	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered empty.	System	06 Oct 2020 16:30:58

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
Un-reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
Un-reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered '06 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
Un-reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered '16:32'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '06 Aug 2020 16:32'	System	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
Un-reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered '71' in	Kim Calloway (b) (4)	13 Aug 2020 19:06:43
DataPoint set to visible.	(b) (4) System	06 Aug 2020 21:20:36

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
Un-reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered '254.8' lb	Kim Calloway (b) (4)	13 Aug 2020 19:06:43
DataPoint set to visible.	(b) (4) System	06 Aug 2020 21:20:36

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
Amendment Manager: User entered '35.61169'	System	16 Sep 2020 23:46:33
User entered '35.6'	System	13 Aug 2020 19:06:43
DataPoint set to visible.	System	06 Aug 2020 21:20:36

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'kg/m2'	System	13 Aug 2020 19:06:43
DataPoint set to visible.	System	06 Aug 2020 21:20:36

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 06:55:28
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Oct 2020 04:39:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 04:39:57
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' answered with '!' (Site from DM).	April Green (b) (4) (b) (4)	01 Oct 2020 19:59:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 19:59:19
User entered 'NS' (non-conformant).	April Green (b) (4) (b) (4)	01 Oct 2020 19:59:19
Un-reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visits performed on the same day then TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP data will be recorded on Predose Vital Sign form of Visit 1 Day 1 visit and will be updated as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:40:05
User entered '98.3' F	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kim Calloway (b) (4)	02 Oct 2020 04:39:57
Un-reviewed for Data Management.	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered 'Oral (Oral)'	Kim Calloway (b) (4)	13 Aug 2020 19:06:43
	(b) (4)	

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
Un-reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4), (b) (6)	28 Sep 2020 12:24:02
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Oct 2020 19:59:19
Un-reviewed for Data Management.	April Green (b) (4)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4)	28 Sep 2020 12:24:02
User entered '84'	(b) (4), (b) (6)	28 Sep 2020 12:24:02
	Kim Calloway (b) (4)	13 Aug 2020 19:06:43
	(b) (4)	

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'bpm'	System	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Oct 2020 19:59:19
Un-reviewed for Data Management.	April Green (b) (4)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4)	28 Sep 2020 12:24:02
User entered '20'	(b) (4), (b) (6)	28 Sep 2020 12:24:02
	Kim Calloway (b) (4)	13 Aug 2020 19:06:43
	(b) (4)	

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'breaths/min'	System	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Oct 2020 19:59:19
Un-reviewed for Data Management.	April Green (b) (4)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4)	28 Sep 2020 12:24:02
User entered '138'	(b) (4), (b) (6)	28 Sep 2020 12:24:02
	Kim Calloway (b) (4)	13 Aug 2020 19:06:43
	(b) (4)	

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'mmHg'	System	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Oct 2020 19:59:19
Un-reviewed for Data Management.	April Green (b) (4)	28 Sep 2020 12:24:10
Reviewed for Data Management.	(b) (4)	28 Sep 2020 12:24:02
User entered '96'	(b) (4), (b) (6)	13 Aug 2020 19:06:43
	Kim Calloway (b) (4)	
	(b) (4)	

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'mmHg'	System	13 Aug 2020 19:06:43

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59

US3452295

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59

US3452295

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:20:49

US3452295

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 07:19:46
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 17:28:26
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	26 Aug 2020 23:42:00
Comment added 'DATE IS CORRECT'.	Kim Calloway (b) (4)	26 Aug 2020 12:02:31
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	18 Aug 2020 20:42:51
User entered '06 Aug 2020'	Kim Calloway (b) (4)	06 Aug 2020 21:20:49

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:56
	(b) (4)	

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:54

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)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	Kim Calloway (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:54

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)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	Kim Calloway (b) (4)	06 Aug 2020 23:48:56

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:56

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Folder: Screening

Form: Risk of Exposure

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[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)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	Kim Calloway (b) (4)	06 Aug 2020 23:48:56

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Folder: Screening

Form: Risk of Exposure

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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)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	Kim Calloway (b) (4)	06 Aug 2020 23:48:56

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Folder: Screening

Form: Risk of Exposure

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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)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	Kim Calloway (b) (4)	06 Aug 2020 23:48:56

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Folder: Screening

Form: Risk of Exposure

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[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)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:56

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Folder: Screening

Form: Risk of Exposure

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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)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	Kim Calloway (b) (4)	06 Aug 2020 23:48:56

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	Kim Calloway (b) (4)	06 Aug 2020 23:48:56

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 23:48:56
	(b) (4)	

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 23:48:56
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'I'	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 23:48:56
	(b) (4)	

US3452295

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:54

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)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	Kim Calloway (b) (4)	06 Aug 2020 23:48:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:54

[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)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:54

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)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	Kim Calloway (b) (4)	06 Aug 2020 23:48:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 23:48:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '0'	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 23:48:56
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:47:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 23:48:56
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	Kim Calloway (b) (4)	06 Aug 2020 21:21:09

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '06 Aug 2020'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:21:09

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4)	06 Aug 2020 21:21:09

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'VISIT1'	System	06 Aug 2020 21:21:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:19:15

US3452295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 02:43:13
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:43:13
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 21:19:15
User entered '101810' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:19:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 21:19:15

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:54

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)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	Kim Calloway (b) (4)	06 Aug 2020 21:21:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:54

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)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	Kim Calloway (b) (4)	06 Aug 2020 21:21:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:21:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:54

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	Kim Calloway (b) (4)	06 Aug 2020 21:21:18

US3452295

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:47:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:21:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 11:26:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 04:39:26
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' answered with '.' (Site from DM).	April Green (b) (4) (b) (4)	01 Oct 2020 20:00:09
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:40:27
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:07:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 04:39:26
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 11:26:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 04:39:26
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' answered with '.' (Site from DM).	April Green (b) (4) (b) (4)	01 Oct 2020 20:00:09
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:40:27
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:07:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 04:39:26
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User accepted default value 'Pre-Dose (PREDOSE)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:07:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	April Green (b) (4)	01 Oct 2020 20:01:04
User entered 'No (N)'	(b) (4)	
	Kim Calloway (b) (4)	13 Aug 2020 19:07:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	02 Oct 2020 04:39:06
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Oct 2020 04:39:06
User entered '06 Aug 2020' reason for change: Data Entry Error	Kim Calloway (b) (4)	02 Oct 2020 04:39:06
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	01 Oct 2020 20:01:04
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Oct 2020 20:01:04
User entered '06 Aug 2010' reason for change: Data Entry Error	April Green (b) (4)	01 Oct 2020 20:01:04
User entered empty.	(b) (4)	13 Aug 2020 19:07:00
	Kim Calloway (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '16:32' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 20:01:04
User entered empty.	April Green (b) (4)	01 Oct 2020 20:01:04
	(b) (4)	
	Kim Calloway (b) (4)	13 Aug 2020 19:07:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered '06 Aug 2020 16:32'	System	02 Oct 2020 04:39:06
User entered '06 Aug 2010 16:32'	System	01 Oct 2020 20:01:04
User entered empty.	System	13 Aug 2020 19:07:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '98.3' F reason for change: Data Entry Error	(b) (4)	01 Oct 2020 20:01:04
User entered empty.	April Green (b) (4)	01 Oct 2020 20:01:04
	(b) (4)	
	Kim Calloway (b) (4)	13 Aug 2020 19:07:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 20:01:04
User entered empty.	April Green (b) (4)	01 Oct 2020 20:01:04
	(b) (4)	
	Kim Calloway (b) (4)	13 Aug 2020 19:07:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:07:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '84' reason for change: Data Entry Error	(b) (4)	
	April Green (b) (4)	01 Oct 2020 20:01:04
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	13 Aug 2020 19:07:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'bpm'	System	01 Oct 2020 20:01:04
User entered empty.	System	13 Aug 2020 19:07:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '20' reason for change: Data Entry Error	(b) (4)	
	April Green (b) (4)	01 Oct 2020 20:01:04
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	13 Aug 2020 19:07:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'breaths/min'	System	01 Oct 2020 20:01:04
User entered empty.	System	13 Aug 2020 19:07:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '138' reason for change: Data Entry Error	(b) (4)	
	April Green (b) (4)	01 Oct 2020 20:01:04
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	13 Aug 2020 19:07:00
	(b) (4)	

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'mmHg'	System	01 Oct 2020 20:01:04
User entered empty.	System	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '96' reason for change: Data Entry Error	(b) (4)	
	April Green (b) (4)	01 Oct 2020 20:01:04
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	13 Aug 2020 19:07:00
	(b) (4)	

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'mmHg'	System	01 Oct 2020 20:01:04
User entered empty.	System	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User closed query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 11:26:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Kim Calloway (b) (4) (b) (4)	02 Oct 2020 04:39:26
Query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' answered with '.' (Site from DM).	April Green (b) (4) (b) (4)	01 Oct 2020 20:00:09
User opened query 'Per CDM: Per CCG pg 15-16 Point 3 If subject has Screening and Visit1Day1 visit performed on the same day then HEIGHT and WEIGHT will be recorded as ND on this form. Please verify and amend the data as appropriate or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:40:27
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:07:00

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 04:39:26
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:07:00
	(b) (4)	

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User accepted default value 'Post-Dose (POSTDOSE)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '06 Aug 2020'	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:13:18
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).		13 Aug 2020 19:08:16
User entered '17:26'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered '06 Aug 2020 17:26'	System	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '98.2' F	Kim Calloway (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Oral (Oral)'	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '81'	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'bpm'	System	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '15'	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'breaths/min'	System	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '135'	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'mmHg'	System	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '91'	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'mmHg'	System	13 Aug 2020 19:08:16

US3452295

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	Kim Calloway (b) (4)	06 Aug 2020 21:21:28

US3452295

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '06 Aug 2020'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:21:28

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	Kim Calloway (b) (4)	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '06 Aug 2020'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '16:46'	(b) (4) Kim Calloway (b) (4)	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered '06 Aug 2020 16:46'	System	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Left Arm (LEFT ARM)'	Kim Calloway (b) (4)	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'ONCE'	System	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 21:56:27

US3452295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 19:08:56

US3452295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '06 Aug 2020'	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:08:56

US3452295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '16:40'	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:08:56

US3452295

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered '06 Aug 2020 16:40'	System	13 Aug 2020 19:08:56

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:47:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '06 Aug 2020'	Kim Calloway (b) (4)	13 Aug 2020 19:09:15

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kim Calloway (b) (4)	13 Aug 2020 19:09:15

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:09:15

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '16:37'	Kim Calloway (b) (4)	13 Aug 2020 19:09:15

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered '06 Aug 2020 16:37'	System	13 Aug 2020 19:09:15

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:09:31

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	13 Aug 2020 19:09:31

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '16:37'	Kim Calloway (b) (4)	13 Aug 2020 19:09:31

US3452295

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered '06 Aug 2020 16:37'	System	13 Aug 2020 19:09:31

US3452295

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Kim Calloway (b) (4)	13 Aug 2020 19:16:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Kim Calloway (b) (4)	13 Aug 2020 19:16:35
User entered 'Yes (Y)'	(b) (4)	
	Kim Calloway (b) (4)	06 Aug 2020 21:21:36
	(b) (4)	

US3452295

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered '1'	System	13 Aug 2020 19:16:51
User entered empty.	System	13 Aug 2020 19:16:35
User entered '1'	System	06 Aug 2020 21:21:36

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:22:27', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '05d040fb-f625-4877-aac4-7d422ec51e64' User entered 'Yes (Y)'	System	06 Aug 2020 22:22:51
	System	06 Aug 2020 22:22:51

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:22:35', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '05d040fb-f625-4877-aac4-7d422ec51e64' User entered '98.2'	System	06 Aug 2020 22:22:51
	System	06 Aug 2020 22:22:51

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:22:39', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '05d040fb-f625-4877-aac4-7d422ec51e64'	System	06 Aug 2020 22:22:51
User entered 'No (N)'	System	06 Aug 2020 22:22:51

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:22:48', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '05d040fb-f625-4877-aac4-7d422ec51e64' User entered '06 Aug 2020 17:22'	System	06 Aug 2020 22:22:51
	System	06 Aug 2020 22:22:51

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '06 Aug 2020 17:06'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '06 Aug 2020 19:36'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:31:26', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'b2f759e6-27a2-4dd9-8944-e55d8528520b' User entered 'Yes (Y)'	System	07 Aug 2020 01:31:48
	System	07 Aug 2020 01:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:31:33', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'b2f759e6-27a2-4dd9-8944-e55d8528520b' User entered '97.5'	System	07 Aug 2020 01:31:48
	System	07 Aug 2020 01:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:31:37', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'b2f759e6-27a2-4dd9-8944-e55d8528520b' User entered 'No (N)'	System	07 Aug 2020 01:31:48
	System	07 Aug 2020 01:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:31:43', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'b2f759e6-27a2-4dd9-8944-e55d8528520b' User entered '06 Aug 2020 20:31'	System	07 Aug 2020 01:31:48
	System	07 Aug 2020 01:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '06 Aug 2020 20:31'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 2'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:47:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:10', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'dd3b8542-0a3a-4cc4-8de4-609f256fb7af'	System	07 Aug 2020 23:45:42
User entered 'Yes (Y)'	System	07 Aug 2020 23:45:42

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:47:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:16', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'dd3b8542-0a3a-4cc4-8de4-609f256fb7af' User entered '99.9'	System	07 Aug 2020 23:45:42
	System	07 Aug 2020 23:45:42

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:20', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'dd3b8542-0a3a-4cc4-8de4-609f256fb7af'	System	07 Aug 2020 23:45:42
User entered 'Yes (Y)'	System	07 Aug 2020 23:45:42

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User closed query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 19:25:46
Query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' answered with 'SUBJECT WAS CONTACTED' (Site from DM).	Kim Calloway (b) (4) (b) (4)	27 Aug 2020 11:42:10
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).	(b) (4), (b) (6)	17 Aug 2020 15:33:18
User opened query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 15:33:13
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 'Added' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:27:47
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).	System	07 Aug 2020 23:45:42

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:31', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'dd3b8542-0a3a-4cc4-8de4-609f256fb7af' User entered '1'	System	07 Aug 2020 23:45:42
	System	07 Aug 2020 23:45:42

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:47:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:31', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'dd3b8542-0a3a-4cc4-8de4-609f256fb7af' User entered '0'	System	07 Aug 2020 23:45:42
	System	07 Aug 2020 23:45:42

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:40', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'dd3b8542-0a3a-4cc4-8de4-609f256fb7af' User entered '07 Aug 2020 18:45'	System	07 Aug 2020 23:45:42
	System	07 Aug 2020 23:45:42

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 3'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:47:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:12', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '18c9a879-8f78-49c0-8196-4c057aef5f4f' User entered 'Yes (Y)'	System	09 Aug 2020 05:35:43
	System	09 Aug 2020 05:35:43

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:47:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:20', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '18c9a879-8f78-49c0-8196-4c057aef5f4f' User entered '100.5'	System	09 Aug 2020 05:35:43
	System	09 Aug 2020 05:35:43

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:24', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '18c9a879-8f78-49c0-8196-4c057aef5f4f' User entered 'Yes (Y)'	System	09 Aug 2020 05:35:43
	System	09 Aug 2020 05:35:43

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User closed query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 19:25:51
Query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' answered with 'SUBJECT WAS CONTACTED' (Site from DM).	Kim Calloway (b) (4) (b) (4)	27 Aug 2020 11:42:21
User opened query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 15:33:32
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).	(b) (4), (b) (6)	17 Aug 2020 15:33:24
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 'added' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:27:58
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).	System	09 Aug 2020 05:35:43

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:34', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '18c9a879-8f78-49c0-8196-4c057aef5f4f' User entered '1'	System	09 Aug 2020 05:35:43
	System	09 Aug 2020 05:35:43

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:47:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:34', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '18c9a879-8f78-49c0-8196-4c057aef5f4f' User entered '0'	System	09 Aug 2020 05:35:43
	System	09 Aug 2020 05:35:43

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:42', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '18c9a879-8f78-49c0-8196-4c057aef5f4f' User entered '09 Aug 2020 00:35'	System	09 Aug 2020 05:35:43
	System	09 Aug 2020 05:35:43

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 4'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:47:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:57:41', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '14bdf6ea-2bb6-4a47-87ca-072d105d98a3' User entered 'Yes (Y)'	System	10 Aug 2020 02:58:04
	System	10 Aug 2020 02:58:04

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:47:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:57:47', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '14bdf6ea-2bb6-4a47-87ca-072d105d98a3' User entered '97.7'	System	10 Aug 2020 02:58:04
	System	10 Aug 2020 02:58:04

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:57:51', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '14bdf6ea-2bb6-4a47-87ca-072d105d98a3'	System	10 Aug 2020 02:58:04
User entered 'Yes (Y)'	System	10 Aug 2020 02:58:04

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User closed query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 19:25:55
Query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' answered with 'SUBJECT WAS CONTACTED' (Site from DM).	Kim Calloway (b) (4) (b) (4)	27 Aug 2020 11:42:34
User opened query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 15:33:53
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).	(b) (4), (b) (6)	17 Aug 2020 15:33:38
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 'added' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:28:07
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).	System	10 Aug 2020 02:58:04

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:57:58', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '14bdf6ea-2bb6-4a47-87ca-072d105d98a3' User entered '1'	System	10 Aug 2020 02:58:04
	System	10 Aug 2020 02:58:04

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:47:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:57:58', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '14bdf6ea-2bb6-4a47-87ca-072d105d98a3' User entered '0'	System	10 Aug 2020 02:58:04
	System	10 Aug 2020 02:58:04

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:02', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '14bdf6ea-2bb6-4a47-87ca-072d105d98a3' User entered '09 Aug 2020 21:58'	System	10 Aug 2020 02:58:04
	System	10 Aug 2020 02:58:04

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 5'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:47:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:14', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '92d7ec19-e39e-4572-bd76-24654b28cce8' User entered 'Yes (Y)'	System	10 Aug 2020 22:40:52
	System	10 Aug 2020 22:40:52

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:47:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:21', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '92d7ec19-e39e-4572-bd76-24654b28cce8' User entered '98.3'	System	10 Aug 2020 22:40:52
	System	10 Aug 2020 22:40:52

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:40', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '92d7ec19-e39e-4572-bd76-24654b28cce8' User entered 'Yes (Y)'	System	10 Aug 2020 22:40:52
	System	10 Aug 2020 22:40:52

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:43', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '92d7ec19-e39e-4572-bd76-24654b28cce8' User entered '0'	System	10 Aug 2020 22:40:52
	System	10 Aug 2020 22:40:52

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:47:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User closed query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 19:26:04
Query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' answered with 'SUBJECT WAS CONTACTED' (Site from DM).	Kim Calloway (b) (4) (b) (4)	27 Aug 2020 11:42:48
User opened query 'Per CDM, please clarify what was updated per previous query. Subject reported medication to treat pain or fever however no Prior/Concomitant Medication is present for pain or fever. Please complete page or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 15:34:05
User closed query 'Per the participant response, medication was taken to prevent 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).	(b) (4), (b) (6)	17 Aug 2020 15:34:00
Query 'Per the participant response, medication was taken to prevent 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 'added' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 14:28:15
User opened query 'Per the participant response, medication was taken to prevent 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).	System	10 Aug 2020 22:40:52

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:47:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:43', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '92d7ec19-e39e-4572-bd76-24654b28cce8' User entered '1'	System	10 Aug 2020 22:40:52
	System	10 Aug 2020 22:40:52

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:48', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '92d7ec19-e39e-4572-bd76-24654b28cce8' User entered '10 Aug 2020 17:40'	System	10 Aug 2020 22:40:52
	System	10 Aug 2020 22:40:52

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 6'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:47:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:07', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '06b6563d-b8cd-4c33-92da-b50899f65601' User entered 'Yes (Y)'	System	12 Aug 2020 04:57:33
	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:47:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:16', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '06b6563d-b8cd-4c33-92da-b50899f65601' User entered '98.0'	System	12 Aug 2020 04:57:33
	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:20', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '06b6563d-b8cd-4c33-92da-b50899f65601'	System	12 Aug 2020 04:57:33
User entered 'Yes (Y)'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:24', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '06b6563d-b8cd-4c33-92da-b50899f65601' User entered '0'	System	12 Aug 2020 04:57:33
	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:47:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'SUBJECT WAS CONTACTED' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 19:26:10
User opened query 'Per the participant response, medication was taken to prevent 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).	Kim Calloway (b) (4)	27 Aug 2020 11:43:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:24', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '06b6563d-b8cd-4c33-92da-b50899f65601'	(b) (4)	
User entered '1'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:29', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '06b6563d-b8cd-4c33-92da-b50899f65601' User entered '11 Aug 2020 23:57'	System	12 Aug 2020 04:57:33
	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 7'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:47:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:03', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1895c0a4-0cc9-4104-872e-26e6989d26f4' User entered 'Yes (Y)'	System	13 Aug 2020 09:04:24
	System	13 Aug 2020 09:04:24

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:47:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:11', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1895c0a4-0cc9-4104-872e-26e6989d26f4' User entered '98.0'	System	13 Aug 2020 09:04:24
	System	13 Aug 2020 09:04:24

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:15', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1895c0a4-0cc9-4104-872e-26e6989d26f4' User entered 'Yes (Y)'	System	13 Aug 2020 09:04:24
	System	13 Aug 2020 09:04:24

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:19', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1895c0a4-0cc9-4104-872e-26e6989d26f4' User entered '0'	System	13 Aug 2020 09:04:24
	System	13 Aug 2020 09:04:24

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:47:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'SUBJECT WAS CONTACTED' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 19:26:14
User opened query 'Per the participant response, medication was taken to prevent 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).	Kim Calloway (b) (4)	27 Aug 2020 11:43:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:19', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1895c0a4-0cc9-4104-872e-26e6989d26f4'	(b) (4)	
User entered '1'	System	13 Aug 2020 09:04:24
	System	13 Aug 2020 09:04:24
	System	13 Aug 2020 09:04:24

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:22', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1895c0a4-0cc9-4104-872e-26e6989d26f4' User entered '13 Aug 2020 04:04'	System	13 Aug 2020 09:04:24
	System	13 Aug 2020 09:04:24

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	12 Aug 2020 04:57:33
User entered 'Day 8'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:47:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T21:31:33', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c11a1693-e847-42e1-b38c-fd28120d4b11' User entered 'Yes (Y)'	System	14 Aug 2020 02:31:48
	System	14 Aug 2020 02:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:47:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T21:31:39', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c11a1693-e847-42e1-b38c-fd28120d4b11' User entered '97.8'	System	14 Aug 2020 02:31:48
	System	14 Aug 2020 02:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T21:31:43', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c11a1693-e847-42e1-b38c-fd28120d4b11'	System	14 Aug 2020 02:31:48
User entered 'No (N)'	System	14 Aug 2020 02:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T21:31:46', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c11a1693-e847-42e1-b38c-fd28120d4b11' User entered '13 Aug 2020 21:31'	System	14 Aug 2020 02:31:48
	System	14 Aug 2020 02:31:48

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:22:56', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '0c9c02d0-23cd-4109-b57e-ae27d98c9def' User entered 'None (1)'	System	06 Aug 2020 22:23:16
	System	06 Aug 2020 22:23:16

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:01', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '0c9c02d0-23cd-4109-b57e-ae27d98c9def' User entered 'No (N)'	System	06 Aug 2020 22:23:16
	System	06 Aug 2020 22:23:16

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:05', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '0c9c02d0-23cd-4109-b57e-ae27d98c9def' User entered 'No (N)'	System	06 Aug 2020 22:23:16
	System	06 Aug 2020 22:23:16

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:10', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '0c9c02d0-23cd-4109-b57e-ae27d98c9def' User entered 'None (1)'	System	06 Aug 2020 22:23:16
	System	06 Aug 2020 22:23:16

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:13', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '0c9c02d0-23cd-4109-b57e-ae27d98c9def' User entered '06 Aug 2020 17:23'	System	06 Aug 2020 22:23:16
	System	06 Aug 2020 22:23:16

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '06 Aug 2020 17:06'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '06 Aug 2020 19:36'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:31:56', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '459377b4-b7b8-4aea-82ef-b95a8f3292fc' User entered 'None (1)'	System	07 Aug 2020 01:32:19
	System	07 Aug 2020 01:32:19

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:02', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '459377b4-b7b8-4aea-82ef-b95a8f3292fc' User entered 'No (N)'	System	07 Aug 2020 01:32:19
	System	07 Aug 2020 01:32:19

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:06', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '459377b4-b7b8-4aea-82ef-b95a8f3292fc' User entered 'No (N)'	System	07 Aug 2020 01:32:19
	System	07 Aug 2020 01:32:19

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:10', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '459377b4-b7b8-4aea-82ef-b95a8f3292fc' User entered 'None (1)'	System	07 Aug 2020 01:32:19
	System	07 Aug 2020 01:32:19

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:15', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '459377b4-b7b8-4aea-82ef-b95a8f3292fc' User entered '06 Aug 2020 20:32'	System	07 Aug 2020 01:32:19
	System	07 Aug 2020 01:32:19

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '06 Aug 2020 20:31'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 2'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:49', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '16f33936-7a95-4a7a-8b3a-62a1c220bca2'	System	07 Aug 2020 23:48:14
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 23:48:14

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:47:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:54', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '16f33936-7a95-4a7a-8b3a-62a1c220bca2' User entered 'No (N)'	System	07 Aug 2020 23:48:14
	System	07 Aug 2020 23:48:14

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:45:59', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '16f33936-7a95-4a7a-8b3a-62a1c220bca2' User entered 'Yes (Y)'	System	07 Aug 2020 23:48:14
	System	07 Aug 2020 23:48:14

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:47:54

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:47:53', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '16f33936-7a95-4a7a-8b3a-62a1c220bca2' User entered '30'	System	07 Aug 2020 23:48:14
	System	07 Aug 2020 23:48:14

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:47:57', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '16f33936-7a95-4a7a-8b3a-62a1c220bca2' User entered 'None (1)'	System	07 Aug 2020 23:48:14
	System	07 Aug 2020 23:48:14

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:13', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '16f33936-7a95-4a7a-8b3a-62a1c220bca2' User entered '07 Aug 2020 18:48'	System	07 Aug 2020 23:48:14
	System	07 Aug 2020 23:48:14

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 3'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:51', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '052af00e-cd42-40f1-b1bb-147c5a3c475d' User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 05:36:09
	System	09 Aug 2020 05:36:09

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:47:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:55', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '052af00e-cd42-40f1-b1bb-147c5a3c475d' User entered 'No (N)'	System	09 Aug 2020 05:36:09
	System	09 Aug 2020 05:36:09

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:35:58', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '052af00e-cd42-40f1-b1bb-147c5a3c475d' User entered 'No (N)'	System	09 Aug 2020 05:36:09
	System	09 Aug 2020 05:36:09

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:03', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '052af00e-cd42-40f1-b1bb-147c5a3c475d' User entered 'None (1)'	System	09 Aug 2020 05:36:09
	System	09 Aug 2020 05:36:09

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:08', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '052af00e-cd42-40f1-b1bb-147c5a3c475d' User entered '09 Aug 2020 00:36'	System	09 Aug 2020 05:36:09
	System	09 Aug 2020 05:36:09

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 4'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:08', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '4dc1fd7d-b7ad-4f8d-aa0d-20f9f1a81c6b'	System	10 Aug 2020 02:58:29
User entered 'None (1)'	System	10 Aug 2020 02:58:29

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:47:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:12', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '4dc1fd7d-b7ad-4f8d-aa0d-20f9f1a81c6b' User entered 'No (N)'	System	10 Aug 2020 02:58:29
	System	10 Aug 2020 02:58:29

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:15', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '4dc1fd7d-b7ad-4f8d-aa0d-20f9f1a81c6b' User entered 'No (N)'	System	10 Aug 2020 02:58:29
	System	10 Aug 2020 02:58:29

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:23', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '4dc1fd7d-b7ad-4f8d-aa0d-20f9f1a81c6b' User entered 'None (1)'	System	10 Aug 2020 02:58:29
	System	10 Aug 2020 02:58:29

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:27', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '4dc1fd7d-b7ad-4f8d-aa0d-20f9f1a81c6b' User entered '09 Aug 2020 21:58'	System	10 Aug 2020 02:58:29
	System	10 Aug 2020 02:58:29

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 5'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:54', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '5c01bb56-ec95-4f7c-b5d1-3774211ec039'	System	10 Aug 2020 22:41:15
User entered 'None (1)'	System	10 Aug 2020 22:41:15

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:47:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:40:58', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '5c01bb56-ec95-4f7c-b5d1-3774211ec039' User entered 'No (N)'	System	10 Aug 2020 22:41:15
	System	10 Aug 2020 22:41:15

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:01', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '5c01bb56-ec95-4f7c-b5d1-3774211ec039'	System	10 Aug 2020 22:41:15
User entered 'No (N)'	System	10 Aug 2020 22:41:15

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:05', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '5c01bb56-ec95-4f7c-b5d1-3774211ec039' User entered 'None (1)'	System	10 Aug 2020 22:41:15
	System	10 Aug 2020 22:41:15

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:10', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '5c01bb56-ec95-4f7c-b5d1-3774211ec039' User entered '10 Aug 2020 17:41'	System	10 Aug 2020 22:41:15
	System	10 Aug 2020 22:41:15

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 6'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:33', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3bab0007-123a-4fa7-80ab-aaa25c832d13'	System	12 Aug 2020 04:57:47
User entered 'None (1)'	System	12 Aug 2020 04:57:47

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:47:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:36', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3bab0007-123a-4fa7-80ab-aaa25c832d13' User entered 'No (N)'	System	12 Aug 2020 04:57:47
	System	12 Aug 2020 04:57:47

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:39', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3bab0007-123a-4fa7-80ab-aaa25c832d13' User entered 'No (N)'	System	12 Aug 2020 04:57:47
	System	12 Aug 2020 04:57:47

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:42', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3bab0007-123a-4fa7-80ab-aaa25c832d13' User entered 'None (1)'	System	12 Aug 2020 04:57:47
	System	12 Aug 2020 04:57:47

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:46', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3bab0007-123a-4fa7-80ab-aaa25c832d13' User entered '11 Aug 2020 23:57'	System	12 Aug 2020 04:57:47
	System	12 Aug 2020 04:57:47

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 7'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:27', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd0919936-2891-40d1-855c-4e37d7bba542'	System	13 Aug 2020 09:04:48
User entered 'None (1)'	System	13 Aug 2020 09:04:48

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:47:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:33', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd0919936-2891-40d1-855c-4e37d7bba542'	System	13 Aug 2020 09:04:48
User entered 'No (N)'	System	13 Aug 2020 09:04:48

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:36', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd0919936-2891-40d1-855c-4e37d7bba542'	System	13 Aug 2020 09:04:48
User entered 'No (N)'	System	13 Aug 2020 09:04:48

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:47:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:41', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd0919936-2891-40d1-855c-4e37d7bba542'	System	13 Aug 2020 09:04:48
User entered 'None (1)'	System	13 Aug 2020 09:04:48

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:47:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:44', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd0919936-2891-40d1-855c-4e37d7bba542'	System	13 Aug 2020 09:04:48
User entered '13 Aug 2020 04:04'	System	13 Aug 2020 09:04:48

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:22', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9' User entered 'None (0)'	System	06 Aug 2020 22:23:49
	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:27', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9' User entered 'None (0)'	System	06 Aug 2020 22:23:49
	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:29', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9' User entered 'None (0)'	System	06 Aug 2020 22:23:49
	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:32', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9' User entered 'None (0)'	System	06 Aug 2020 22:23:49
	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:34', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9' User entered 'None (0)'	System	06 Aug 2020 22:23:49
	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:36', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9' User entered 'None (0)'	System	06 Aug 2020 22:23:49
	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:41', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9' User entered 'No (N)'	System	06 Aug 2020 22:23:49
	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T17:23:43', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c15ba55c-cd59-4592-a611-652db534d8d9' User entered '06 Aug 2020 17:23'	System	06 Aug 2020 22:23:49
	System	06 Aug 2020 22:23:49

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '06 Aug 2020 17:06'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '06 Aug 2020 19:36'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:22', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830' User entered 'None (0)'	System	07 Aug 2020 01:33:05
	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:27', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830' User entered 'None (0)'	System	07 Aug 2020 01:33:05
	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:32', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830' User entered 'None (0)'	System	07 Aug 2020 01:33:05
	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:38', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830' User entered 'None (0)'	System	07 Aug 2020 01:33:05
	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:41', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830' User entered 'None (0)'	System	07 Aug 2020 01:33:05
	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:43', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830' User entered 'None (0)'	System	07 Aug 2020 01:33:05
	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:49', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830' User entered 'No (N)'	System	07 Aug 2020 01:33:05
	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-06T20:32:57', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a048205b-f55d-4311-aeff-03090eb55830' User entered '06 Aug 2020 20:32'	System	07 Aug 2020 01:33:05
	System	07 Aug 2020 01:33:05

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '06 Aug 2020 20:31'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 2'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:20', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f' User entered 'No interference with activity (1)'	System	07 Aug 2020 23:49:06
	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:26', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f' User entered 'Some interference with activity (2)'	System	07 Aug 2020 23:49:06
	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:31', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f' User entered 'No interference with activity (1)'	System	07 Aug 2020 23:49:06
	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:45', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f' User entered 'None (0)'	System	07 Aug 2020 23:49:06
	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:48', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f' User entered 'None (0)'	System	07 Aug 2020 23:49:06
	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:48:53', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f' User entered 'None (0)'	System	07 Aug 2020 23:49:06
	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:49:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f' User entered 'No (N)'	System	07 Aug 2020 23:49:06
	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-07T18:49:04', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'e6227668-0d2f-4db9-b785-09aca13f137f' User entered '07 Aug 2020 18:49'	System	07 Aug 2020 23:49:06
	System	07 Aug 2020 23:49:06

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 3'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:18', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7' User entered 'None (0)'	System	09 Aug 2020 05:36:57
	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:23', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7'	System	09 Aug 2020 05:36:57
User entered 'Some interference with activity (2)'	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:29', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7'	System	09 Aug 2020 05:36:57
User entered 'Some interference with activity (2)'	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:33', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7'	System	09 Aug 2020 05:36:57
User entered 'Some interference with activity (2)'	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:36', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7' User entered 'None (0)'	System	09 Aug 2020 05:36:57
	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:40', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7'	System	09 Aug 2020 05:36:57
User entered 'No interference with activity (1)'	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:52', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7' User entered 'No (N)'	System	09 Aug 2020 05:36:57
	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T00:36:55', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '3acced3c-6206-4df8-9b2e-43255723e0d7' User entered '09 Aug 2020 00:36'	System	09 Aug 2020 05:36:57
	System	09 Aug 2020 05:36:57

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 4'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:58:33', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40' User entered 'None (0)'	System	10 Aug 2020 03:00:07
	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:59:08', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40'	System	10 Aug 2020 03:00:07
User entered 'No interference with activity (1)'	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:59:23', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40'	System	10 Aug 2020 03:00:07
User entered 'No interference with activity (1)'	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:59:28', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40' User entered 'None (0)'	System	10 Aug 2020 03:00:07
	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:59:32', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40' User entered 'None (0)'	System	10 Aug 2020 03:00:07
	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:59:42', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40'	System	10 Aug 2020 03:00:07
User entered 'No interference with activity (1)'	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T21:59:50', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40' User entered 'No (N)'	System	10 Aug 2020 03:00:07
	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-09T22:00:03', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '8230c780-9851-4cb3-9799-b3f59f6bfc40' User entered '09 Aug 2020 22:00'	System	10 Aug 2020 03:00:07
	System	10 Aug 2020 03:00:07

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 5'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:16', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604' User entered 'None (0)'	System	10 Aug 2020 22:41:53
	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:20', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604'	System	10 Aug 2020 22:41:53
User entered 'No interference with activity (1)'	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:26', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604'	System	10 Aug 2020 22:41:53
User entered 'No interference with activity (1)'	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:31', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604' User entered 'None (0)'	System	10 Aug 2020 22:41:53
	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:34', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604' User entered 'None (0)'	System	10 Aug 2020 22:41:53
	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:40', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604'	System	10 Aug 2020 22:41:53
User entered 'Some interference with activity not requiring medical attention (2)'	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:46', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604' User entered 'No (N)'	System	10 Aug 2020 22:41:53
	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-10T17:41:49', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd210289a-38bb-40b0-be74-0e55ac1c6604' User entered '10 Aug 2020 17:41'	System	10 Aug 2020 22:41:53
	System	10 Aug 2020 22:41:53

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 6'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:51', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834' User entered 'None (0)'	System	12 Aug 2020 04:58:19
	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:55', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834'	System	12 Aug 2020 04:58:19
User entered 'No interference with activity (1)'	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:57:59', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834'	System	12 Aug 2020 04:58:19
User entered 'No interference with activity (1)'	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:58:02', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834' User entered 'None (0)'	System	12 Aug 2020 04:58:19
	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:58:04', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834' User entered 'None (0)'	System	12 Aug 2020 04:58:19
	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:58:08', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834' User entered 'None (0)'	System	12 Aug 2020 04:58:19
	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:58:14', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834' User entered 'No (N)'	System	12 Aug 2020 04:58:19
	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-11T23:58:16', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75c049d-5542-4c9e-b62c-5624f655c834' User entered '11 Aug 2020 23:58'	System	12 Aug 2020 04:58:19
	System	12 Aug 2020 04:58:19

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 7'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:50', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2' User entered 'None (0)'	System	13 Aug 2020 09:05:14
	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:52', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2' User entered 'None (0)'	System	13 Aug 2020 09:05:14
	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:55', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2' User entered 'None (0)'	System	13 Aug 2020 09:05:14
	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:04:58', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2' User entered 'None (0)'	System	13 Aug 2020 09:05:14
	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2' User entered 'None (0)'	System	13 Aug 2020 09:05:14
	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:05:03', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2' User entered 'None (0)'	System	13 Aug 2020 09:05:14
	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:05:07', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2'	System	13 Aug 2020 09:05:14
User entered 'No (N)'	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T04:05:11', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '19113b9a-aa2d-48fb-8e55-4ecaf13bbdc2' User entered '13 Aug 2020 04:05'	System	13 Aug 2020 09:05:14
	System	13 Aug 2020 09:05:14

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	12 Aug 2020 04:57:33
User entered 'Day 8'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T21:31:52', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '7fb722fe-b83e-4d8a-a202-7e39cf19b2f4'	System	14 Aug 2020 02:31:59
User entered 'No (N)'	System	14 Aug 2020 02:31:59

US3452295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:47:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-08-13T21:31:58', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '7fb722fe-b83e-4d8a-a202-7e39cf19b2f4' User entered '13 Aug 2020 21:31'	System	14 Aug 2020 02:31:59
	System	14 Aug 2020 02:31:59

US3452295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:47:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 04:57:33

US3452295

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:47:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 04:57:33

US3452295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:51:43
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:43:16

US3452295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:51:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:43:16

US3452295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:51:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:43:16

US3452295

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:51:43
User entered 'ND Patient moved to Convalescent Period'	(b) (4), (b) (6)	20 Oct 2020 19:43:16

US3452295

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:51:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:29:45

US3452295

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'I'	System	24 Sep 2020 15:29:45

US3452295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:51:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:43:25

US3452295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:51:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:43:25

US3452295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:51:57
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:43:25

US3452295

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:51:57
User entered 'ND Patient moved to Convalescent Period'	(b) (4), (b) (6)	20 Oct 2020 19:43:25

US3452295

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:52:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:29:54

US3452295

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'I'	System	24 Sep 2020 15:29:54

US3452295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:43:36

US3452295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:43:36

US3452295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:43:36

US3452295

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'ND Patient moved to Convalescent Period'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:43:36

US3452295

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:30:04

US3452295

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'I'	System	24 Sep 2020 15:30:04

US3452295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:36:09

US3452295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '10 Sep 2020'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:36:09

US3452295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Clinic (Clinic)'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:36:09

US3452295

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'VISIT2'	System	09 Oct 2020 16:36:09

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User accepted default value 'Pre-Dose (PREDOSE)'	Kim Calloway (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '10 Sep 2020'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '11:39'	Kim Calloway (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered '10 Sep 2020 11:39'	System	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '98.2' F	Kim Calloway (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Oral (Oral)'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '72'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'bpm'	System	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '20'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'breaths/min'	System	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '148'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'mmHg'	System	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '84'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'mmHg'	System	09 Oct 2020 16:35:47

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User accepted default value 'Post-Dose (POSTDOSE)'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	09 Oct 2020 16:35:54

US3452295

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:31:17

US3452295

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:31:17

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User closed query 'Per CDM: Since the subject has discontinued from the IP dosing. Please review and update the Dosing Discontinuation form under End of study visit. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:29:58
Query 'Per CDM: Since the subject has discontinued from the IP dosing. Please review and update the Dosing Discontinuation form under End of study visit. Thank you.' answered with 'UPDATED' (Site from DM).	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 17:17:12
User opened query 'Per CDM: Since the subject has discontinued from the IP dosing. Please review and update the Dosing Discontinuation form under End of study visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 05:56:05
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Confirmed COVID-19 (COVID)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	24 Sep 2020 15:30:44

US3452295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:38:49

US3452295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '10 Sep 2020'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:38:49

US3452295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '11:41'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:38:49

US3452295

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered '10 Sep 2020 11:41'	System	09 Oct 2020 16:38:49

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:47:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '10 Sep 2020'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kim Calloway (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '11:43'	Kim Calloway (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:47:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered '10 Sep 2020 11:43'	System	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kim Calloway (b) (4) (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:47:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	09 Oct 2020 16:44:59

US3452295

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:31:25

US3452295

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'I'	System	24 Sep 2020 15:31:25

US3452295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:31:58

US3452295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:31:58

US3452295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:31:58

US3452295

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:31:58

US3452295

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:32:05

US3452295

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'I'	System	24 Sep 2020 15:32:05

US3452295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:32:20

US3452295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:32:20

US3452295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:32:20

US3452295

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:32:20

US3452295

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:57:21

US3452295

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'I'	System	02 Oct 2020 14:57:21

US3452295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:57:33

US3452295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:57:33

US3452295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:57:33

US3452295

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:57:33

US3452295

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	Kim Calloway (b) (4)	02 Oct 2020 17:00:55

US3452295

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'I'	System	02 Oct 2020 17:00:55

US3452295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:11

US3452295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '2 Oct 2020'	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:11

US3452295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4)	02 Oct 2020 17:01:11

US3452295

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'VISIT3'	System	02 Oct 2020 17:01:11

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'No (N)'	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered empty.	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered empty.	System	02 Oct 2020 17:01:19

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39

US3452295

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39

US3452295

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	Kim Calloway (b) (4)	02 Oct 2020 17:01:35

US3452295

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '2 Oct 2020'	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:01:35

US3452295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:02:23

US3452295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '2 Oct 2020'	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:02:23

US3452295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered '11:25'	(b) (4) Kim Calloway (b) (4)	02 Oct 2020 17:02:23

US3452295

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered '2 Oct 2020 11:25'	System	02 Oct 2020 17:02:23

US3452295

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	17 Feb 2021 18:16:20
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4)	05 Nov 2020 14:42:57
	(b) (4)	

US3452295

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'I'	System	05 Nov 2020 14:42:57

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 64'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Have you been exposed to someone with 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)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Please 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)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Please 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)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Please 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)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:19:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 71'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-10-15T12:01:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '287940a8-599a-4a78-b411-b1d9463f726f' User entered 'No (N)'	System	15 Oct 2020 17:01:30
	System	15 Oct 2020 17:01:30

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-10-15T12:01:05', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '287940a8-599a-4a78-b411-b1d9463f726f' User entered 'No (N)'	System	15 Oct 2020 17:01:30
	System	15 Oct 2020 17:01:30

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-10-15T12:01:10', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '287940a8-599a-4a78-b411-b1d9463f726f' User entered '15 Oct 2020 12:01:10'	System	15 Oct 2020 17:01:30
	System	15 Oct 2020 17:01:30

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 78'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-10-24T03:49:47', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1dc670b0-49a0-4c10-92d3-b03a4b79261f' User entered 'No (N)'	System	24 Oct 2020 08:50:08
	System	24 Oct 2020 08:50:08

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-10-24T03:49:54', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1dc670b0-49a0-4c10-92d3-b03a4b79261f'	System	24 Oct 2020 08:50:08
User entered 'No (N)'	System	24 Oct 2020 08:50:08

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-10-24T03:50:03', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '1dc670b0-49a0-4c10-92d3-b03a4b79261f' User entered '24 Oct 2020 03:50:03'	System	24 Oct 2020 08:50:08
	System	24 Oct 2020 08:50:08

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 92'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-03T05:15:09', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'fd8b7971-06da-408e-bb75-7b046d6aa974' User entered 'No (N)'	System	03 Nov 2020 11:15:22
	System	03 Nov 2020 11:15:22

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-03T05:15:14', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'fd8b7971-06da-408e-bb75-7b046d6aa974' User entered 'No (N)'	System	03 Nov 2020 11:15:22
	System	03 Nov 2020 11:15:22

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-03T05:15:18', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'fd8b7971-06da-408e-bb75-7b046d6aa974' User entered '03 Nov 2020 05:15:18'	System	03 Nov 2020 11:15:22
	System	03 Nov 2020 11:15:22

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 99'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-12T12:01:41', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c7f12d1a-8f75-43ca-a097-29756e6fa819' User entered 'No (N)'	System	12 Nov 2020 18:01:54
	System	12 Nov 2020 18:01:54

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-12T12:01:46', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c7f12d1a-8f75-43ca-a097-29756e6fa819'	System	12 Nov 2020 18:01:54
User entered 'No (N)'	System	12 Nov 2020 18:01:54

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-12T12:01:50', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c7f12d1a-8f75-43ca-a097-29756e6fa819' User entered '12 Nov 2020 12:01:50'	System	12 Nov 2020 18:01:54
	System	12 Nov 2020 18:01:54

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered 'Day 106'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-17T05:53:57', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd418b29a-8810-4f1a-bde1-f3128d921ffe' User entered 'No (N)'	System	17 Nov 2020 11:55:48
	System	17 Nov 2020 11:55:48

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-17T05:54:04', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd418b29a-8810-4f1a-bde1-f3128d921ffe'	System	17 Nov 2020 11:55:48
User entered 'No (N)'	System	17 Nov 2020 11:55:48

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-17T05:54:09', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd418b29a-8810-4f1a-bde1-f3128d921ffe' User entered '17 Nov 2020 05:54:09'	System	17 Nov 2020 11:55:48
	System	17 Nov 2020 11:55:48

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 21:56:27

US3452295

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:07:44
Data entry locked.	System	06 Aug 2020 21:56:27
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 21:56:27

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-24T03:39:31', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75406c8-7d6b-461f-a30c-65fbcaec0a76'	System	24 Nov 2020 09:39:47
User entered 'No (N)'	System	24 Nov 2020 09:39:47

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Have you been exposed to someone with 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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-24T03:39:37', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75406c8-7d6b-461f-a30c-65fbcaec0a76'	System	24 Nov 2020 09:39:47
User entered 'No (N)'	System	24 Nov 2020 09:39:47

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-24T03:39:44', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'a75406c8-7d6b-461f-a30c-65fbcaec0a76' User entered '24 Nov 2020 03:39:44'	System	24 Nov 2020 09:39:47
	System	24 Nov 2020 09:39:47

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:15:19', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered 'Yes (Y)'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Have you been exposed to someone with 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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:15:27', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered 'No (N)'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered 'Yes (Y)'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '1'	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '1'	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:25', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '0'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Please 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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:44', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b'	System	28 Nov 2020 07:17:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:16:57', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered 'No (N)'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-11-28T01:17:26', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'ab384034-fe41-4ad4-a856-45b67fb0de7b' User entered '28 Nov 2020 01:17:26'	System	28 Nov 2020 07:17:38
	System	28 Nov 2020 07:17:38

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-12-05T04:50:48', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c72ec0c6-1866-4a81-ab88-c5a110701588' User entered 'No (N)'	System	05 Dec 2020 10:51:05
	System	05 Dec 2020 10:51:05

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Have you been exposed to someone with 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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-12-05T04:50:54', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c72ec0c6-1866-4a81-ab88-c5a110701588' User entered 'No (N)'	System	05 Dec 2020 10:51:05
	System	05 Dec 2020 10:51:05

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-12-05T04:51:01', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'c72ec0c6-1866-4a81-ab88-c5a110701588' User entered '05 Dec 2020 04:51:01'	System	05 Dec 2020 10:51:05
	System	05 Dec 2020 10:51:05

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-12-12T12:42:01', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '235470d0-0a79-426a-b2d5-fe2fab773e0d' User entered 'No (N)'	System	12 Dec 2020 18:42:10
	System	12 Dec 2020 18:42:10

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Have you been exposed to someone with 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 (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-12-12T12:42:04', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '235470d0-0a79-426a-b2d5-fe2fab773e0d' User entered 'No (N)'	System	12 Dec 2020 18:42:10
	System	12 Dec 2020 18:42:10

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F119437-2141-4CE2-94DC-0E4A8E323E0B)', Time: '2020-12-12T12:42:07', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '235470d0-0a79-426a-b2d5-fe2fab773e0d' User entered '12 Dec 2020 12:42:07'	System	12 Dec 2020 18:42:10
	System	12 Dec 2020 18:42:10

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-03-15T12:32:53-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'de9bf67e-c02d-479c-9bda-8311e321ca65'	System	15 Mar 2021 17:33:08
User entered 'No (N)'	System	15 Mar 2021 17:33:08

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Have you been exposed to someone with 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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-03-15T12:32:58-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'de9bf67e-c02d-479c-9bda-8311e321ca65'	System	15 Mar 2021 17:33:08
User entered 'No (N)'	System	15 Mar 2021 17:33:08

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-03-15T12:33:02-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'de9bf67e-c02d-479c-9bda-8311e321ca65'	System	15 Mar 2021 17:33:08
User entered '15 Mar 2021 12:33:02'	System	15 Mar 2021 17:33:08

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-03-23T20:57:28-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'aa2ee08d-00ad-4952-b3f6-63ed341b3aff'	System	24 Mar 2021 01:57:41
User entered 'No (N)'	System	24 Mar 2021 01:57:41

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Have you been exposed to someone with 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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-03-23T20:57:34-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'aa2ee08d-00ad-4952-b3f6-63ed341b3aff'	System	24 Mar 2021 01:57:41
User entered 'No (N)'	System	24 Mar 2021 01:57:41

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-03-23T20:57:39-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'aa2ee08d-00ad-4952-b3f6-63ed341b3aff' User entered '23 Mar 2021 20:57:39'	System	24 Mar 2021 01:57:41
	System	24 Mar 2021 01:57:41

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-03-27T00:02:22-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '6d869cd4-554c-4c54-bb80-f9b3445faa80'	System	27 Mar 2021 05:02:33
User entered 'No (N)'	System	27 Mar 2021 05:02:33

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Have you been exposed to someone with 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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-03-27T00:02:26-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '6d869cd4-554c-4c54-bb80-f9b3445faa80'	System	27 Mar 2021 05:02:33
User entered 'No (N)'	System	27 Mar 2021 05:02:33

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-03-27T00:02:30-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '6d869cd4-554c-4c54-bb80-f9b3445faa80' User entered '27 Mar 2021 00:02:30'	System	27 Mar 2021 05:02:33
	System	27 Mar 2021 05:02:33

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-04-04T12:09:59-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd5dff451-eb10-47b5-8d28-8512808959de' User entered 'No (N)'	System	04 Apr 2021 17:10:13
	System	04 Apr 2021 17:10:13

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Have you been exposed to someone with 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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-04-04T12:10:03-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd5dff451-eb10-47b5-8d28-8512808959de'	System	04 Apr 2021 17:10:13
User entered 'No (N)'	System	04 Apr 2021 17:10:13

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-04-04T12:10:07-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'd5dff451-eb10-47b5-8d28-8512808959de' User entered '04 Apr 2021 12:10:07'	System	04 Apr 2021 17:10:13
	System	04 Apr 2021 17:10:13

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-04-10T02:43:20-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '49f501dd-2f95-4b28-a7b2-6c6fdf627433'	System	10 Apr 2021 07:43:32
User entered 'No (N)'	System	10 Apr 2021 07:43:32

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Have you been exposed to someone with 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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-04-10T02:43:24-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '49f501dd-2f95-4b28-a7b2-6c6fdf627433'	System	10 Apr 2021 07:43:32
User entered 'No (N)'	System	10 Apr 2021 07:43:32

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-04-10T02:43:27-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '49f501dd-2f95-4b28-a7b2-6c6fdf627433'	System	10 Apr 2021 07:43:32
User entered '10 Apr 2021 02:43:27'	System	10 Apr 2021 07:43:32

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-04-17T00:04:12-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '00e55578-5b7c-4a2f-8686-859265cb2fcf'	System	17 Apr 2021 05:04:25
User entered 'No (N)'	System	17 Apr 2021 05:04:25

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Have you been exposed to someone with 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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-04-17T00:04:15-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '00e55578-5b7c-4a2f-8686-859265cb2fcf'	System	17 Apr 2021 05:04:25
User entered 'No (N)'	System	17 Apr 2021 05:04:25

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-04-17T00:04:20-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '00e55578-5b7c-4a2f-8686-859265cb2fcf'	System	17 Apr 2021 05:04:25
User entered '17 Apr 2021 00:04:20'	System	17 Apr 2021 05:04:25

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-04-26T12:03:56-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '658fbb0f-e52c-435a-a52c-f6dfb74a565a' User entered 'No (N)'	System	26 Apr 2021 17:06:56
	System	26 Apr 2021 17:06:56

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

Have you been exposed to someone with 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 (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-04-26T12:04:00-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '658fbb0f-e52c-435a-a52c-f6dfb74a565a' User entered 'No (N)'	System	26 Apr 2021 17:06:56

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-04-26T12:04:03-05:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: '658fbb0f-e52c-435a-a52c-f6dfb74a565a' User entered '26 Apr 2021 12:04:03'	System	26 Apr 2021 17:06:56
	System	26 Apr 2021 17:06:56

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 15:19:44

US3452295

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:47:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:19:44
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 15:19:44

US3452295

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:47:54

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)	26 Apr 2021 12:30:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-03-11T02:53:33-06:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'b11cf1b0-a337-4b65-8869-2f66333a70fb'	System	11 Mar 2021 08:53:41
User entered 'No (N)'	System	11 Mar 2021 08:53:41

US3452295

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:47:54

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:30:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BB025EA1-03A0-47CE-A2CD-B7757E823F59)', Time: '2021-03-11T02:53:39-06:00', User OID: 'PatientReportedOutcome (US3452295)', ODM File OID: 'b11cf1b0-a337-4b65-8869-2f66333a70fb' User entered '11 Mar 2021 02:53:39'	System	11 Mar 2021 08:53:41
	System	11 Mar 2021 08:53:41

US3452295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) Chalimar Rojo (b) (4)	05 Nov 2020 14:43:09

US3452295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '05 Nov 2020'	(b) (4) Chalimar Rojo (b) (4)	05 Nov 2020 14:43:09

US3452295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4)	05 Nov 2020 14:43:09

US3452295

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	Chalimar Rojo (b) (4)	05 Nov 2020 14:43:09

US3452295

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	08 Dec 2020 18:15:30

US3452295

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 04:39:39
User entered 'I'	System	08 Dec 2020 18:15:30

US3452295

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	08 Dec 2020 18:15:43

US3452295

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '8 Dec 2020'	Chalimar Rojo (b) (4)	08 Dec 2020 18:15:43

US3452295

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4)	08 Dec 2020 18:15:43

US3452295

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	Chalimar Rojo (b) (4)	08 Dec 2020 18:15:43

US3452295

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:07:32

US3452295

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User entered 'I'	System	14 Jan 2021 17:07:32

US3452295

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:09:30

US3452295

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '10 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:09:30

US3452295

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:09:30

US3452295

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:09:30

US3452295

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Destiny Heinzig-Cartwright (b) (4)	08 Feb 2021 16:47:23

US3452295

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User entered 'I'	System	08 Feb 2021 16:47:23

US3452295

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:48:47

US3452295

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:48:47

US3452295

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:48:47

US3452295

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:48:47

US3452295

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	11 Feb 2021 15:02:18

US3452295

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:16:36
User entered 'I'	System	11 Feb 2021 15:02:18

US3452295

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:06:48

US3452295

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '09 Mar 2021'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:06:48
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Clinic (Clinic)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:06:48

US3452295

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'VISIT4'	System	09 Mar 2021 19:06:48

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'No (N)'	(b) (4)	
	Kim Calloway (b) (4)	29 Mar 2021 19:58:08
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	29 Mar 2021 19:58:08
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	29 Mar 2021 19:58:08
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User entered empty.	System	29 Mar 2021 19:58:08

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	29 Mar 2021 19:58:08
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	29 Mar 2021 19:58:08
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	29 Mar 2021 19:58:08
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	29 Mar 2021 19:58:08
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User entered empty.	System	29 Mar 2021 19:58:08

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	29 Mar 2021 19:58:08
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User entered empty.	System	29 Mar 2021 19:58:08

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	29 Mar 2021 19:58:08
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User entered empty.	System	29 Mar 2021 19:58:08

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4)	
	Kim Calloway (b) (4)	29 Mar 2021 19:58:08
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55
User entered empty.	System	29 Mar 2021 19:58:08

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55

US3452295

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:24:55

US3452295

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4)	
	Kim Calloway (b) (4)	09 Mar 2021 19:07:01
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '09 Mar 2021'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:07:01
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:07:16
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 09MAR2021 is recorded under Visit 04 Day 209 Visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you ' (Site from DM). Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 09MAR2021 is recorded under Visit 04 Day 209 Visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you ' answered with '09MAR2021 IS CORRECT DATE FOR VISIT 4 DAY 209' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:33:10
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 09MAR2021 is recorded under Visit 04 Day 209 Visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you ' (Site from DM).	Kim Calloway (b) (4) (b) (4)	29 Mar 2021 21:35:52
User entered '09 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 09:02:05
	Kim Calloway (b) (4) (b) (4)	09 Mar 2021 19:07:16

US3452295

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '12:04'	(b) (4)	
	Kim Calloway (b) (4)	09 Mar 2021 19:07:16
	(b) (4)	

US3452295

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered '09 Mar 2021 12:04'	System	09 Mar 2021 19:07:16

US3452295

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:07:18

US3452295

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:22:59
User entered 'I'	System	09 Mar 2021 19:07:18

US3452295

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	12 Apr 2021 14:38:18
	(b) (4)	

US3452295

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
User entered '10 Apr 2021'	Chalimar Rojo (b) (4)	12 Apr 2021 14:38:18
	(b) (4)	

US3452295

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4)	12 Apr 2021 14:38:18
	(b) (4)	

US3452295

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
User entered empty.	Chalimar Rojo (b) (4)	12 Apr 2021 14:38:18
	(b) (4)	

US3452295

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	12 Apr 2021 14:38:25
	(b) (4)	

US3452295

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 14:38:25

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:54

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:04
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:25:54

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:54

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:04
User entered '12:15' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 20:44:23
User entered '12:30'	(b) (4), (b) (6)	18 Aug 2020 20:25:54

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:54

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:09
User entered '10 Aug 2020 12:15'	System	18 Aug 2020 20:44:23
User entered '10 Aug 2020 12:30'	System	18 Aug 2020 20:25:54

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:54

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:04
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4), (b) (6)	18 Aug 2020 20:25:54

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:47:54

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:09
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:25:54

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User closed query 'Per CDM; Please confirm initial start date of symptoms and Contact date are the same (10AUG2020) or update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:56:39
Query 'Per CDM; Please confirm initial start date of symptoms and Contact date are the same (10AUG2020) or update accordingly' answered with 'correct' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:27:59
User opened query 'Per CDM; Please confirm initial start date of symptoms and Contact date are the same (10AUG2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:31:15
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '95'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.2' F	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:29:24

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '11 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '95'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	18 Aug 2020 20:31:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.5' F	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:31:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '12 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 20:39:14

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '13 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97.8' F	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 21:10:12
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 21:10:12
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:04:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '14 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:06:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '15 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97.8' F	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User closed query 'Per source, sore throat is indicated as 'mild'. Please reconcile' (Site from CRA).	(b) (4)	29 Oct 2020 19:11:10
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:11:08
Query 'Per source, sore throat is indicated as 'mild'. Please reconcile' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:05:01
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:04:55
User opened query 'Per source, sore throat is indicated as 'mild'. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:10:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:09:53
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:07:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '16 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '96'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97.4' F	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:10:12

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '17 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '96'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	18 Aug 2020 21:12:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '18 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:10:55

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '19 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '96'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.2' F	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Aug 2020 20:11:36

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	21 Aug 2020 14:17:48

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:30:15
User entered '20 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:29:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:34:36
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:33:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 15:33:30
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 15:30:15
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:30:15

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	24 Aug 2020 15:33:30
User entered empty.	System	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	29 Oct 2020 19:11:59
User closed query 'Per source, body aches is graded as 'none'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:11:57
Query 'Per source, body aches is graded as 'none'. Please reconcile. ' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:05:35
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:05:30
User opened query 'Per source, body aches is graded as 'none'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:18:06
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:17:19
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 15:33:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 15:30:15

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '23 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.1' F	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	24 Aug 2020 15:36:29

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:12:13
User closed query 'Per source, O2 saturation is listed as '97%'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:12:12
Query 'Per source, O2 saturation is listed as '97%'. Please reconcile. ' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:06:45
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:06:38
User opened query 'Per source, O2 saturation is listed as '97%'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:20:17
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	29 Oct 2020 19:12:19
User closed query 'Per source, temperature is listed as '98.0 F'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:12:16
Query 'Per source, temperature is listed as '98.0 F'. Please reconcile. ' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:06:50
User entered '98.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:06:38
User opened query 'Per source, temperature is listed as '98.0 F'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:21:29
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:20:25
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.2' F	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	25 Aug 2020 15:00:30

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '25 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	26 Aug 2020 21:11:03

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:58:10

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '26 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.1' F	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:58:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 18 (Day 18)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '27 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 15:59:43

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 19 (Day 19)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '28 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97.9' F	(b) (4), (b) (6)	31 Aug 2020 16:02:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:02:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	29 Oct 2020 19:12:40
User closed query 'Please indicate whether diarrhea was present. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:12:39
Query 'Please indicate whether diarrhea was present. answered with 'entered ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:11:50
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:11:39
User opened query 'Please indicate whether diarrhea was present. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:23:57
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:23:21
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 16:02:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	29 Oct 2020 19:12:45
User closed query 'Please indicate whether diarrhea was present. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:12:43
Query 'Please indicate whether diarrhea was present. answered with 'entered' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:11:55
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:11:39
User opened query 'Please indicate whether diarrhea was present. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:24:05
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:23:23
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 16:02:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 20 (Day 20)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '29 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	31 Aug 2020 16:08:10

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:08:10

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 21 (Day 21)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '30 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '96'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	31 Aug 2020 16:09:27

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

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Folder: Covid-19 Assessment 10 Aug 2020

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Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	31 Aug 2020 16:09:27

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 22 (Day 22)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '31 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '95'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.2' F	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:02:47

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 23 (Day 23)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '01 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:16:13
User entered '97.' (non-conformant).	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	08 Sep 2020 16:16:13
User entered empty.	System	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	29 Oct 2020 19:13:08
User closed query 'Per source, temperature is listed as '97.8'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:13:06
Query 'Per source, temperature is listed as '97.8'. Please reconcile. ' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:12:36
User entered '97.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:12:29
User opened query 'Per source, temperature is listed as '97.8'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:27:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:26:18
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 16:16:13
User entered '98' F	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:11:49

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 24 (Day 24)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '02 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '96'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	08 Sep 2020 16:16:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.3' F	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:16:13

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 25 (Day 25)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 16:18:32

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 26 (Day 26)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '04 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '98.0' F	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:13:23
User closed query 'Per source, headache is indicated as 'mild'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:13:21
Query 'Per source, headache is indicated as 'mild'. Please reconcile. ' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:13:18
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:13:05
User opened query 'Per source, headache is indicated as 'mild'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:30:01
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:29:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:13:28
User closed query 'Per source, nasal congestion is indicated as 'mild'. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:13:26
Query 'Per source, nasal congestion is indicated as 'mild'. Please reconcile' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 14:13:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:13:05
User opened query 'Per source, nasal congestion is indicated as 'mild'. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:30:42
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:30:20
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:51:22
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:40:17

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Day 27 (Day 27)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 08SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:19:39
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 08SEP2020. Please reconcile or clarify.' answered with 'information is correcte due to the holiday day 28 was oushed out' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:29:13
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 08SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:31:47
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '05 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User entered '%'	System	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered '97.9' F	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Symptom Log (27)

Generated On: 11 Aug 2021 22:47:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:24
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:27
User entered 'None (None)'	(b) (4), (b) (6)	08 Sep 2020 17:51:22

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:54

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:35
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:36
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:54

[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 11:13:35
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:54

[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 11:13:35
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:36
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 13:44:58
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'entered' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 20:40:35
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	18 Aug 2020 20:40:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:54

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:35
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:36
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:54

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:35
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:36
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:54

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:35
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:36
User closed query 'Type of Test performed is not Other, however, Specify is provided. Please review and reconcile.' (Site from System).	System	21 Aug 2020 14:18:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:18:28
User opened query 'Type of Test performed is not Other, however, Specify is provided. Please review and reconcile.' (Site from System).	System	18 Aug 2020 20:40:25
User entered 'Done at clinic visit'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:54

[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 11:13:35
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:36
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	21 Aug 2020 14:18:52
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	21 Aug 2020 14:18:37
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 14:18:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 14:18:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:18:37
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 14:18:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:18:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:35
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:36
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:40:25

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:47:54

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:35
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:18:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:40:25

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Folder: Covid-19 Assessment 10 Aug 2020

Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:35
Amendment Manager: User entered 'I'	System	21 Aug 2020 02:43:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered '16'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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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 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered '95'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

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 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered '95'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

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Generated On: 11 Aug 2021 22:47:54

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

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Generated On: 11 Aug 2021 22:47:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

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Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[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 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

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Generated On: 11 Aug 2021 22:47:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:47:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:49:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:42:05

US3452295

Folder: Covid-19 Assessment 10 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:47:54

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:13:57
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 19:52:21
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 19:43:52

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:47:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:47:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:47:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User closed query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-21 = 08SEP2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF.Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 04:59:16
Query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-21 = 08SEP2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF.Thanks ' answered with 'Dates are correct for each collection day and were sent to the lab on 9/8/2020. Correction will be made with PPD' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:08:43
User opened query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-21 = 08SEP2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF.Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:38:15
User closed query 'Per GCL Lab Recon: Saliva: Per Preclarus report, there seems to be a data entry error in 'PPD GCL' for this Day 3,5,7,9,14,21 Saliva sample collection dates as all are recorded as collected on a single day only, i.e on "08 SEP 2020", which seems to be a data entry error. Please kindly send a DCF to PPD GCL to update the correct sample collection dates in Preclarus PPD portal. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 05:48:45
Query 'Per GCL Lab Recon: Saliva: Per Preclarus report, there seems to be a data entry error in 'PPD GCL' for this Day 3,5,7,9,14,21 Saliva sample collection dates as all are recorded as collected on a single day only, i.e on "08 SEP 2020", which seems to be a data entry error. Please kindly send a DCF to PPD GCL to update the correct sample collection dates in Preclarus PPD portal. Thank you.' answered with 'DCF sent to PPD' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 21:33:09

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:47:54

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: Saliva: Per Preclarus report, there seems to be a data entry error in 'PPD GCL' for this Day 3,5,7,9,14,21 Saliva sample collection dates as all are recorded as collected on a single day only, i.e on "08 SEP 2020", which seems to be a data entry error. Please kindly send a DCF to PPD GCL to update the correct sample collection dates in Preclarus PPD portal. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 18:25:35
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12,14,16,18,23,30AUG2020 is recorded under Illness Visit Day 3,5,7,9,14,21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	(b) (4), (b) (6)	21 Feb 2021 18:24:36
' canceled (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12,14,16,18,23,30AUG2020 is recorded under Illness Visit Day 3,5,7,9,14,21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	(b) (4), (b) (6)	04 Dec 2020 07:38:30
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '12 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:47:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:47:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:47:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '14 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:47:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:47:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:47:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '16 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:47:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:47:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:47:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:47:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:47:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	21 Oct 2020 15:35:18
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 21:03:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 21:03:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 21:03:36
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:47:18
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:47:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '23 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 21:03:36
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:47:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:47:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:35:18
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 16:09:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 16:09:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 16:09:56
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:47:18
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:47:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '30 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 16:09:56
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:47:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:47:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:35:18
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 17:28:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 17:28:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:28:10
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:47:18
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:47:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08SEP2020 is recorded under Illness Visit Day 28 in EDC, however the same is reported under COVID PCR Saliva Day 5 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 07:50:39
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08SEP2020 is recorded under Illness Visit Day 28 in EDC, however the same is reported under COVID PCR Saliva Day 5 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'Labs are correct in EDC. Lab has been called to make corrections. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 18:23:08
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08SEP2020 is recorded under Illness Visit Day 28 in EDC, however the same is reported under COVID PCR Saliva Day 5 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:14:14
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:13:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:20:53
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:20:53
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:35:18
User entered '8 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 17:28:10
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:47:18

US3452295

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:46:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:42:51

US3452295

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User closed query 'Per ETRTR: Please reconcile and confirm date of Illness Visit D1 and procedures according to data in Preclarus Lab Portal' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 17:33:40
Query 'Per ETRTR: Please reconcile and confirm date of Illness Visit D1 and procedures according to data in Preclarus Lab Portal' answered with 'Illness visit was performed on 10-AUG-2020 lab portal is incorrect and has been notified to correct ' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 21:12:52
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 21:46:46
User opened query 'Per ETRTR: Please reconcile and confirm date of Illness Visit D1 and procedures according to data in Preclarus Lab Portal' (Site from CRA).	(b) (4), (b) (6)	20 Aug 2020 22:27:24
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:42:51

US3452295

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[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 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:46:46
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Aug 2020 20:42:51

US3452295

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User entered 'SICKD1'	System	18 Aug 2020 20:42:51

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '12:23'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User entered '10 Aug 2020 12:23'	System	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '71' in	(b) (4), (b) (6)	18 Aug 2020 20:43:59
DataPoint set to visible.	System	18 Aug 2020 20:42:51

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '254.7' lb	(b) (4), (b) (6)	18 Aug 2020 20:43:59
DataPoint set to visible.	System	18 Aug 2020 20:42:51

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '98.2' F	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered 'Oral (Oral)'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:26
User closed query 'per ETRTR: Please confirm clinical significance on Pulse, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Aug 2020 21:47:18
Query 'per ETRTR: Please confirm clinical significance on Pulse, thanks.' answered with 'NSC' (Site from CRA).	Kim Calloway (b) (4) (b) (4)	24 Aug 2020 15:42:02
User opened query 'per ETRTR: Please confirm clinical significance on Pulse, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Aug 2020 21:54:58
User entered '95'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User entered 'bpm'	System	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '16'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User entered 'breaths/min'	System	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:26
User closed query 'Response is noted, however, please indicate CS/NCS' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 06:48:23
Query 'Response is noted, however, please indicate CS/NCS' answered with 'NCS' (Site from DM).	Kim Calloway (b) (4)	24 Aug 2020 15:42:10
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:14:02
User opened query 'Response is noted, however, please indicate CS/NCS' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 19:14:00
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Information is correct' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 20:44:09
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	18 Aug 2020 20:43:59
User entered '159'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User entered 'mmHg'	System	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:26
User entered '95'	(b) (4), (b) (6)	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User entered 'mmHg'	System	18 Aug 2020 20:43:59

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27

US3452295

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27

US3452295

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:45:41

US3452295

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:34
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:45:41

US3452295

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:47:54

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 20:46:33

US3452295

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:47:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:41:27
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 21:47:40
User entered '10 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 20:46:33

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:08
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:28:26

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:08
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:12:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:20:14
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:20:14
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:32
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:28:26

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:08
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:32
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Sep 2020 17:28:26

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:08
User entered 'SICKD28'	System	08 Sep 2020 17:28:26

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:12:23
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:20:24
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:20:24
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '11:35'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User entered '08 Sep 2020 11:35'	System	10 Nov 2020 17:20:24
User entered '8 Sep 2020 11:35'	System	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '71.0' in	(b) (4), (b) (6)	08 Sep 2020 17:37:05
DataPoint set to visible.	System	08 Sep 2020 17:28:26

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '253.9' lb	(b) (4), (b) (6)	08 Sep 2020 17:37:05
DataPoint set to visible.	System	08 Sep 2020 17:28:26

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '98.5' F	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '72'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User entered 'bpm'	System	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '14'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User entered 'breaths/min'	System	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '139'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User entered 'mmHg'	System	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:50:41
User entered '93'	(b) (4), (b) (6)	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05
User entered 'mmHg'	System	08 Sep 2020 17:37:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:05

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:54:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:28:36

US3452295

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:01
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:25:43
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:20:33
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:20:33
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:54:56
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:28:36

US3452295

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:47:54

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:57
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:55:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:28:55

US3452295

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:47:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:57
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:12:53
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:20:42
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:20:42
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:55:04
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:28:55

US3452295

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

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	11 Jan 2021 21:57:38

US3452295

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

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '11 Jan 2021'	Kim Calloway (b) (4)	11 Jan 2021 21:57:38

US3452295

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

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4)	11 Jan 2021 21:57:38

US3452295

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

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 21:57:38

US3452295

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

Form: Unblinding

Generated On: 11 Aug 2021 22:47:54

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '11 Jan 2021'	Kim Calloway (b) (4)	11 Jan 2021 21:58:09

US3452295

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

Form: Unblinding

Generated On: 11 Aug 2021 22:47:54

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:47:31

US3452295

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

Form: Unblinding

Generated On: 11 Aug 2021 22:47:54

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	11 Jan 2021 21:58:09

US3452295

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

Form: Unblinding

Generated On: 11 Aug 2021 22:47:54

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:47:31

US3452295

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

Form: Unblinding

Generated On: 11 Aug 2021 22:47:54

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '11 Jan 2021'	Kim Calloway (b) (4)	11 Jan 2021 21:58:09

US3452295

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

Form: Unblinding

Generated On: 11 Aug 2021 22:47:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Placebo (Placebo)'	Kim Calloway (b) (4)	11 Jan 2021 21:58:09

US3452295

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

Form: Unblinding

Generated On: 11 Aug 2021 22:47:54

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:35:39
User entered 'Placebo (Placebo)'	Kim Calloway (b) (4)	11 Jan 2021 21:58:09
	(b) (4)	

US3452295

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

Form: Unblinding

Generated On: 11 Aug 2021 22:47:54

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:35:39
User entered 'Placebo (Placebo)'	Kim Calloway (b) (4)	11 Jan 2021 21:58:09
	(b) (4)	

US3452295

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

Form: Unblinding

Generated On: 11 Aug 2021 22:47:54

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	11 Jan 2021 21:58:09

US3452295

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

Form: Unblinding

Generated On: 11 Aug 2021 22:47:54

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered '1'	System	11 Jan 2021 21:58:09

US3452295

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

Form: Unblinding

Generated On: 11 Aug 2021 22:47:54

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'I'	System	11 Jan 2021 21:58:09

US3452295

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 00:35:02
User entered empty.	Kim Calloway (b) (4)	11 Jan 2021 22:07:20
	(b) (4)	

US3452295

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 00:35:02
User entered empty.	Kim Calloway (b) (4)	11 Jan 2021 22:07:20
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered empty.	System	11 Jan 2021 22:07:20
DataPoint set to visible.	System	11 Jan 2021 21:58:09

US3452295

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 00:35:02
User entered empty.	Kim Calloway (b) (4)	11 Jan 2021 22:07:20
	(b) (4)	

US3452295

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 00:35:02
User entered empty.	Kim Calloway (b) (4)	11 Jan 2021 22:07:20
	(b) (4)	

US3452295

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered empty.	System	11 Jan 2021 22:07:20
DataPoint set to visible.	System	11 Jan 2021 21:58:09

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User accepted default value 'Pre-Dose (PREDOSE)'	Kim Calloway (b) (4) (b) (4)	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '11 Jan 2021'	Kim Calloway (b) (4)	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '14:04'	(b) (4) Kim Calloway (b) (4) (b) (4)	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered '11 Jan 2021 14:04'	System	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '98.1' F	Kim Calloway (b) (4)	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Oral (Oral)'	(b) (4) Kim Calloway (b) (4)	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) Kim Calloway (b) (4)	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '71'	(b) (4) Kim Calloway (b) (4)	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'bpm'	System	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '14'	Kim Calloway (b) (4)	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'breaths/min'	System	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '133'	(b) (4) Kim Calloway (b) (4)	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'mmHg'	System	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '87'	(b) (4) Kim Calloway (b) (4)	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'mmHg'	System	12 Jan 2021 00:35:02

US3452295

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 00:35:02
User entered empty.	Kim Calloway (b) (4)	11 Jan 2021 22:07:20
	(b) (4)	

US3452295

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 00:35:02
User entered empty.	Kim Calloway (b) (4)	11 Jan 2021 22:07:20
	(b) (4)	

US3452295

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:47:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered empty.	System	11 Jan 2021 22:07:20
DataPoint set to visible.	System	11 Jan 2021 21:58:09

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User accepted default value 'Post-Dose (POSTDOSE)'	Kim Calloway (b) (4) (b) (4)	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '11 Jan 2021'	Kim Calloway (b) (4)	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '14:55'	(b) (4) Kim Calloway (b) (4)	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered '11 Jan 2021 14:55'	System	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '36.6' C	Kim Calloway (b) (4)	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Oral (Oral)'	(b) (4) Kim Calloway (b) (4)	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) Kim Calloway (b) (4)	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '71'	Kim Calloway (b) (4)	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'bpm'	System	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '13'	(b) (4) Kim Calloway (b) (4)	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'breaths/min'	System	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '125'	(b) (4) Kim Calloway (b) (4)	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'mmHg'	System	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '79'	Kim Calloway (b) (4)	11 Jan 2021 22:07:20

US3452295

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'mmHg'	System	11 Jan 2021 22:07:20

US3452295

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Kim Calloway (b) (4)	11 Jan 2021 22:07:36

US3452295

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '11 Jan 2021'	Kim Calloway (b) (4)	11 Jan 2021 22:07:36

US3452295

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

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Kim Calloway (b) (4)	11 Jan 2021 22:07:53

US3452295

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

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) Kim Calloway (b) (4) (b) (4)	11 Jan 2021 22:07:53

US3452295

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

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	Kim Calloway (b) (4)	11 Jan 2021 22:07:53

US3452295

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

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'mRNA-1273'	System	11 Jan 2021 22:07:53
DataPoint set to visible.	System	11 Jan 2021 21:58:09

US3452295

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

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '11 Jan 2021'	Kim Calloway (b) (4)	11 Jan 2021 22:07:53

US3452295

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

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '14:25'	Kim Calloway (b) (4)	11 Jan 2021 22:07:53

US3452295

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

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered '11 Jan 2021 14:25'	System	11 Jan 2021 22:07:53

US3452295

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

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Left Arm (LEFT ARM)'	Kim Calloway (b) (4)	11 Jan 2021 22:07:53

US3452295

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

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'ONCE'	System	11 Jan 2021 22:07:53

US3452295

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

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 22:07:53

US3452295

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Kim Calloway (b) (4)	12 Jan 2021 00:35:17

US3452295

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '11 Jan 2021'	(b) (4) Kim Calloway (b) (4)	12 Jan 2021 00:35:17

US3452295

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '14:07'	Kim Calloway (b) (4)	12 Jan 2021 00:35:17

US3452295

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered '11 Jan 2021 14:07'	System	12 Jan 2021 00:35:17

US3452295

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:47:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Kim Calloway (b) (4)	12 Jan 2021 00:35:27

US3452295

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:47:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '11 Jan 2021'	(b) (4) Kim Calloway (b) (4) (b) (4)	12 Jan 2021 00:35:27

US3452295

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:47:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '14:06'	(b) (4) Kim Calloway (b) (4) (b) (4)	12 Jan 2021 00:35:27

US3452295

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered '11 Jan 2021 14:06'	System	12 Jan 2021 00:35:27

US3452295

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

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Kim Calloway (b) (4)	11 Jan 2021 22:08:14

US3452295

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

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered '1'	System	11 Jan 2021 22:08:14

US3452295

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	19 Jan 2021 20:51:56

US3452295

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '19 Jan 2021'	(b) (4) Chalimar Rojo (b) (4) (b) (4)	19 Jan 2021 20:51:56

US3452295

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4)	19 Jan 2021 20:51:56

US3452295

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	Chalimar Rojo (b) (4)	19 Jan 2021 20:51:56

US3452295

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Kim Calloway (b) (4)	08 Feb 2021 18:57:15

US3452295

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'I'	System	08 Feb 2021 18:57:15

US3452295

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered '1'	System	08 Feb 2021 18:57:15
DataPoint set to visible.	System	08 Feb 2021 18:57:15

US3452295

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Kim Calloway (b) (4)	08 Feb 2021 18:57:38

US3452295

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '08 Feb 2021'	(b) (4) Kim Calloway (b) (4)	08 Feb 2021 18:57:38

US3452295

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4)	08 Feb 2021 18:57:38

US3452295

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'OLD29'	System	08 Feb 2021 18:57:38

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User accepted default value 'Pre-Dose (PREDOSE)'	Kim Calloway (b) (4) (b) (4)	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '08 Feb 2021'	Kim Calloway (b) (4)	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '12:16'	Kim Calloway (b) (4)	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered '08 Feb 2021 12:16'	System	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '97.3' F	Kim Calloway (b) (4)	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Oral (Oral)'	(b) (4) Kim Calloway (b) (4) (b) (4)	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) Kim Calloway (b) (4)	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '83'	(b) (4) Kim Calloway (b) (4) (b) (4)	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'bpm'	System	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '16'	(b) (4) Kim Calloway (b) (4) (b) (4)	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'breaths/min'	System	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '132'	(b) (4) Kim Calloway (b) (4)	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'mmHg'	System	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '80'	Kim Calloway (b) (4)	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:47:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'mmHg'	System	08 Feb 2021 18:58:32

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User accepted default value 'Post-Dose (POSTDOSE)'	Kim Calloway (b) (4) (b) (4)	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Kim Calloway (b) (4)	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '08 Feb 2021'	(b) (4) Kim Calloway (b) (4)	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '13:01'	Kim Calloway (b) (4)	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered '08 Feb 2021 13:01'	System	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '98.4' F	Kim Calloway (b) (4)	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Oral (Oral)'	Kim Calloway (b) (4)	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) Kim Calloway (b) (4)	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '76'	Kim Calloway (b) (4)	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'bpm'	System	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '16'	Kim Calloway (b) (4)	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'breaths/min'	System	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '117'	Kim Calloway (b) (4)	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'mmHg'	System	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '77'	Kim Calloway (b) (4)	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:47:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'mmHg'	System	08 Feb 2021 19:21:07

US3452295

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Kim Calloway (b) (4)	08 Feb 2021 18:59:46

US3452295

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '08 Feb 2021'	Kim Calloway (b) (4)	08 Feb 2021 18:59:46

US3452295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	08 Feb 2021 19:00:37

US3452295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	Kim Calloway (b) (4)	08 Feb 2021 19:00:37

US3452295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	Kim Calloway (b) (4)	08 Feb 2021 19:00:37

US3452295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'mRNA-1273'	System	08 Feb 2021 19:00:37
DataPoint set to visible.	System	08 Feb 2021 18:57:15

US3452295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '08 Feb 2021'	(b) (4) Kim Calloway (b) (4)	08 Feb 2021 19:00:37

US3452295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '12:31'	(b) (4) Kim Calloway (b) (4)	08 Feb 2021 19:00:37

US3452295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered '08 Feb 2021 12:31'	System	08 Feb 2021 19:00:37

US3452295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Left Arm (LEFT ARM)'	Kim Calloway (b) (4)	08 Feb 2021 19:00:37

US3452295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'ONCE'	System	08 Feb 2021 19:00:37

US3452295

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 19:00:37

US3452295

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Kim Calloway (b) (4)	08 Feb 2021 19:00:40

US3452295

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'I'	System	08 Feb 2021 19:00:40

US3452295

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	15 Feb 2021 17:19:39

US3452295

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '15 Feb 2021'	Chalimar Rojo (b) (4)	15 Feb 2021 17:19:39

US3452295

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Contact Made (CONTACT MADE)'	Chalimar Rojo (b) (4)	15 Feb 2021 17:19:39

US3452295

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:47:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	Chalimar Rojo (b) (4)	15 Feb 2021 17:19:39

US3452295

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Chalimar Rojo (b) (4)	15 Feb 2021 17:19:25

US3452295

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:47:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'I'	System	15 Feb 2021 17:19:25

US3452295

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Kim Calloway (b) (4)	09 Mar 2021 19:07:34

US3452295

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '09 Mar 2021'	Kim Calloway (b) (4)	09 Mar 2021 19:07:34

US3452295

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Clinic (Clinic)'	Kim Calloway (b) (4)	09 Mar 2021 19:07:34

US3452295

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:47:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered 'OLD57'	System	09 Mar 2021 19:07:34

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'No (N)'	Kim Calloway (b) (4)	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	Kim Calloway (b) (4)	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	Kim Calloway (b) (4)	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered empty.	System	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:07:51

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered empty.	System	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:07:51

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered empty.	System	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered empty.	System	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered empty.	Kim Calloway (b) (4)	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered empty.	System	09 Mar 2021 19:07:51

US3452295

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:47:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13

US3452295

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:07:57

US3452295

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:47:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '09 Mar 2021'	Kim Calloway (b) (4)	09 Mar 2021 19:07:57

US3452295

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered 'Yes (Y)'	Kim Calloway (b) (4)	09 Mar 2021 19:08:05

US3452295

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 09MAR2021 is recorded under Participant Decision Visit / OL-D57 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:31:27
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 09MAR2021 is recorded under Participant Decision Visit / OL-D57 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' answered with '09MAR2021 IS CORRECT FOR OL-D57' (Site from DM).	Kim Calloway (b) (4) (b) (4)	29 Mar 2021 19:59:08
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 09MAR2021 is recorded under Participant Decision Visit / OL-D57 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 12:24:46
User entered '09 Mar 2021'	Kim Calloway (b) (4) (b) (4)	09 Mar 2021 19:08:05

US3452295

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
User entered '12:04'	(b) (4) Kim Calloway (b) (4)	09 Mar 2021 19:08:05

US3452295

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:08:13
User entered '09 Mar 2021 12:04'	System	09 Mar 2021 19:08:05

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:47:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:01:50
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:42:57
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
User closed query 'Per MM, Please review and update the severity. If the AE is worsening of a concurrent Medical History condition, then the severity of the AE should be greater than mild. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:41:11
Query 'Per MM, Please review and update the severity. If the AE is worsening of a concurrent Medical History condition, then the severity of the AE should be greater than mild. ' answered with 'SUBJECT REPORTED WORSENING WAS MILD' (Site from DM).	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 19:32:51
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
User opened query 'Per MM, Please review and update the severity. If the AE is worsening of a concurrent Medical History condition, then the severity of the AE should be greater than mild. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:33:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Esophageal reflux aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 21:49:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 21:49:49
Data point term sent to Coder	System	21 Sep 2020 21:49:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
Data point term sent to Coder	System	21 Sep 2020 21:45:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Esophageal reflux aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 12:15:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 12:15:25
Data point term sent to Coder	(b) (4)	18 Aug 2020 18:24:53
Coding entries removed.	System	18 Aug 2020 18:23:55
	(b) (4), (b) (6)	
User entered 'Worsening of ACID REFLUX' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 19:46:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	13 Aug 2020 19:45:47
User entered 'ACID REFLUX'	Kim Calloway (b) (4)	13 Aug 2020 19:45:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 12:57:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' answered with 'corrected' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 21:44:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 21:43:58
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).	(b) (4), (b) (6)	09 Sep 2020 14:08:02
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 18:10:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 18:10:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:10:44
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 18:07:40
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:07:40
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:13:22
User entered '06 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
User closed query 'Per CDM: Per your previous response "unknown". However, the Event started 7Aug2020 just after the day of dosing 06Aug2020. Please confirm if the event started within 24 hrs of dosing then update a best estimated time or confirm in the response if the event started after 24 hrs of the Dosing. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:41:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
Query 'Per CDM: Per your previous response "unknown". However, the Event started 7Aug2020 just after the day of dosing 06Aug2020. Please confirm if the event started within 24 hrs of dosing then update a best estimated time or confirm in the response if the event started after 24 hrs of the Dosing. Thank you.' answered with 'TIME IS UNKNOWN' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:15:53
User opened query 'Per CDM: Per your previous response "unknown". However, the Event started 7Aug2020 just after the day of dosing 06Aug2020. Please confirm if the event started within 24 hrs of dosing then update a best estimated time or confirm in the response if the event started after 24 hrs of the Dosing. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:29:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Per CDM, please confirm that Adverse Event started exactly in midnight (00:00), otherwise amend where applicable.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 11:33:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 11:33:08
Query 'Per CDM, please confirm that Adverse Event started exactly in midnight (00:00), otherwise amend where applicable.' answered with 'unknown' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:10:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 18:08:01
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:07:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:07:40
User opened query 'Per CDM, please confirm that Adverse Event started exactly in midnight (00:00), otherwise amend where applicable.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 14:13:27
User entered '00:00'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	System	08 Sep 2020 18:07:40
User entered '07 Aug 2020 00:00'	System	18 Aug 2020 18:13:22
User entered '06 Aug 2020 00:00'	System	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '08:00' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '13 Aug 2020 08:00'	System	18 Aug 2020 18:23:55
User entered empty.	System	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
User closed query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1/Mild. Please confirm/update the severity or delete the AE if unchanged from baseline.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:04:34
Query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1/Mild. Please confirm/update the severity or delete the AE if unchanged from baseline.' answered with 'It has a mild worsening. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 22:01:59
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade 1/Mild. Please confirm/update the severity or delete the AE if unchanged from baseline.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:44:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Not Related (NOT RELATED)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Not Related (NOT RELATED)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'None (NONE)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'I'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:23:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

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 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:45:46

US3452295

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Amendment Manager: User entered '0'	System	21 Aug 2020 02:43:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Amendment Manager: User entered '0'	System	21 Aug 2020 02:43:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:47:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:11:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:03
User entered	System	19 Aug 2020 13:39:54
'USA-US208-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	19 Aug 2020 13:39:54

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:46:23
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)	21 Sep 2020 21:49:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 21:49:49
Data point term sent to Coder	(b) (4)	
DataPoint activated with code reason code Data required.	System	21 Sep 2020 21:49:05
	(b) (4), (b) (6)	21 Sep 2020 21:48:14
Data point term sent to Coder	System	21 Sep 2020 21:45:59
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:01:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:01:06
Data point term sent to Coder	(b) (4)	
User entered 'COVID-19'	System	18 Aug 2020 17:47:20
	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 20:53:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 20:53:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 20:53:01
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 13:55:30
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 13:55:30
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'PV Query: Please confirm that the patient tested positive for COVID-19 on 06 Aug 2020 or provide the signs/symptoms the subject experienced on this date. If the subject did not test positive on 06 Aug and was not experiencing any symptoms on this date, please consider updating event start date.' (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 15:38:51
Query 'PV Query: Please confirm that the patient tested positive for COVID-19 on 06 Aug 2020 or provide the signs/symptoms the subject experienced on this date. If the subject did not test positive on 06 Aug and was not experiencing any symptoms on this date, please consider updating event start date.' answered with 'Patient tested positive at screening on 06-AUG-2020' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 20:54:22
User opened query 'PV Query: Please confirm that the patient tested positive for COVID-19 on 06 Aug 2020 or provide the signs/symptoms the subject experienced on this date. If the subject did not test positive on 06 Aug and was not experiencing any symptoms on this date, please consider updating event start date.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:55:14
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:36:17
User entered '13 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 18:37:31
User entered '16:40' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 18:37:31
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 18:36:17
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Aug 2020 17:47:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 17:47:24
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Aug 2020 17:47:04
User entered '12:00'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '06 Aug 2020 16:40'	System	18 Aug 2020 18:37:31
User entered empty.	System	18 Aug 2020 17:47:24
User entered '13 Aug 2020 12:00'	System	18 Aug 2020 17:47:04

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	08 Sep 2020 18:16:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:16:30
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	08 Sep 2020 18:14:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'PV Query: Please provide the event end date (the end date of COVID-19 symptoms).' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 02:23:16
Query 'PV Query: Please provide the event end date (the end date of COVID-19 symptoms).' answered with 'entered' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 18:14:42
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:14:26
User opened query 'PV Query: Please provide the event end date (the end date of COVID-19 symptoms).' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:03:11
User closed query 'PV Query: Please provide the event end date.' (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 15:38:58
Query 'PV Query: Please provide the event end date.' answered with 'Are you wanting an end date for symptoms or for a negative test result?' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 20:59:47
User opened query 'PV Query: Please provide the event end date.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:54:24
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 11:21:37
Query 'Data is required. Please provide.' answered with 'unknow' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 18:16:43
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 18:16:30
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	System	18 Aug 2020 17:47:04

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

US3452295

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 19:13:02
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'Deleted' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 17:47:32
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	18 Aug 2020 17:47:04
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
User closed query 'Per CDM: Response to this data point needs to be recorded if the subject has "Requires inpatient or prolongation of existing Hospitalization" marked as yes. Since the event is not and SAE, please verify and amend the data as appropriate. Thank you.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:41:38
Query 'Per CDM: Response to this data point needs to be recorded if the subject has "Requires inpatient or prolongation of existing Hospitalization" marked as yes. Since the event is not and SAE, please verify and amend the data as appropriate. Thank you.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 17:46:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 02:17:49
User opened query 'Per CDM: Response to this data point needs to be recorded if the subject has "Requires inpatient or prolongation of existing Hospitalization" marked as yes. Since the event is not and SAE, please verify and amend the data as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:17:41
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Sep 2020 10:06:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 21:45:40
		18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:46:23
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:27:10
Reviewed for Data Management.	(b) (4), (b) (6)	23 Sep 2020 08:46:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 21:44:46
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 21:44:46
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 21:44:46
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	08 Sep 2020 18:14:26
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 13:58:05
User closed query 'Per CDM requery: Per your response. Please update the data under END of Study visit Dosing Discontinuation form. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:43:06
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with '	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 19:33:59

COORDINATOR WAS TOLD TO FILL OUT THIS WAY DUE TO PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. HE RETURNED WITHIN 72 HOURS FOR ILLNESS VISIT. SYMPTOMS AND CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. PATIENT TESTED POSITIVE AT SCREENING DATE 06-AUG-2020 AND RESULTS WERE RECEIVED 13-AUG-2020 AND AGAIN ON 10-AUG-2020. NO FURTHER TESTING HAS BEEN DONE. POSITIVE REULT CONFIRMED ON 17-AUG-2020. 1ST VACCINE WAS RECEIVED ON 06-AUG-2020 HOWEVER THE 2ND VACCINE WILL NOT BE GIVEN' (Site from System).

User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	07 Oct 2020 19:32:18
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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		07 Oct 2020 19:30:07
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	07 Oct 2020 19:30:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	07 Oct 2020 17:16:50
Query 'Per CDM query: Per your response. Please update the data under END of Study visit Dosing Discontinuation form. Thank you.' answered with 'MEDICATION IS LISTED' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:18:56
User opened query 'Per CDM query: Per your response. Please update the data under END of Study visit Dosing Discontinuation form. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:10:27
User closed query 'Per CDM: Action Taken is recorded as 'Investigational Product Withdrawn', however Dosing Discontinuation page has not been completed. Please enter page.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:10:27
Query 'Per CDM: Action Taken is recorded as 'Investigational Product Withdrawn', however Dosing Discontinuation page has not been completed. Please enter page.' answered with 'Where is the dosing discontinuation page' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 22:03:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User opened query 'Per CDM: Action Taken is recorded as 'Investigational Product Withdrawn', however Dosing Discontinuation page has not been completed. Please enter page.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 13:00:19

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EAB) (1725)

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Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 02:23:11
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'pt will not receive 2nd vaccine' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 18:15:24
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:14:26
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:04:27
User entered 'None (NONE)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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None

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
User closed query 'Per CDM re-query: Response states 'Medication has been listed', however there is no corresponding medication recorded with an Indication of Covid-19. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM). Query 'Per CDM re-query: Response states 'Medication has been listed', however there is no corresponding medication recorded with an Indication of Covid-19. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' answered with 'SEE CONMEDS' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 13:57:19
User opened query 'Per CDM re-query: Response states 'Medication has been listed', however there is no corresponding medication recorded with an Indication of Covid-19. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:52:30
User opened query 'Per CDM re-query: Response states 'Medication has been listed', however there is no corresponding medication recorded with an Indication of Covid-19. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:45:08
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:45:08
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'MEDICATION HAS BEEN LISTED' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:19:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:46:16
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered 'I'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 02:23:25
Query 'PV Query: Please provide the final event outcome, when available.' answered with 'this is entered' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 18:17:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:14:26
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:54:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	13 Mar 2021 17:20:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:46:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
User closed query 'Per ETRTR: COVID + Narrative should describe clinical presentation/course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 17:35:29
User closed query 'PV Query: Please confirm the study drug was administered prior to positive test result being available.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 02:23:30
User closed query 'PV Query: Thank you for confirming the nasopharyngeal swab from 06 Aug 2020 (screening) was positive. Please provide the date the results came back positive.' (Site from Safety).	(b) (4), (b) (6)	10 Sep 2020 02:23:27
Query 'PV Query: Please confirm the study drug was administered prior to positive test result being available.' answered with 'confirmed and updated' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 18:19:28
User entered 'PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. HE RETURNED WITHIN 72 HOURS FOR ILLNESS VISIT. SYMPTOMS AND CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. PATIENT TESTED POSITIVE AT SCREENING DATE 06-AUG-2020 AND RESULTS WERE RECEIVED 13-AUG-2020 AND AGAIN ON 10-AUG-2020. NO FURTHER TESTING HAS BEEN DONE. POSITIVE RESULT CONFIRMED ON 17-AUG-2020. 1st vaccine was received on 06-Aug-2020 however the 2nd vaccine will not be given' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:19:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Thank you for confirming the nasopharyngeal swab from 06 Aug 2020 (screening) was positive. Please provide the date the results came back positive.' answered with 'added' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 18:18:23
User entered 'PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. HE RETURNED WITHIN 72 HOURS FOR ILLNESS VISIT. SYMPTOMS AND CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. PATIENT TESTED POSITIVE AT SCREENING DATE 06-AUG-2020 and results were received 13-Aug-2020 AND AGAIN ON 10-AUG-2020. NO FURTHER TESTING HAS BEEN DONE. POSITIVE REULT CONFIRMED ON 17-AUG-2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:18:15
User entered 'PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. HE RETURNED WITHIN 72 HOURS FOR ILLNESS VISIT. SYMPTOMS AND CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. PATIENT TESTED POSITIVE AT SCREENING DATE 06-AUG-2020 AND AGAIN ON 10-AUG-2020. NO FURTHER TESTING HAS BEEN DONE. Positive reult confirmed on 17-AUG-2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 18:14:26
User opened query 'PV Query: Please confirm the study drug was administered prior to positive test result being available.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:03:52
User opened query 'PV Query: Thank you for confirming the nasopharyngeal swab from 06 Aug 2020 (screening) was positive. Please provide the date the results came back positive.' (Site from Safety).	(b) (4), (b) (6)	02 Sep 2020 14:03:39
User closed query 'PV Query: Please confirm dates of all COVID-19 swabs, as well as timing of vaccination.' (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 15:39:25
User closed query 'PV Query: Please provide the nasopharyngeal swab results from 06 Aug.' (Site from Safety).	(b) (4), (b) (6)	28 Aug 2020 15:39:11

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm dates of all COVID-19 swabs, as well as timing of vaccination.' answered with 'entered' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 20:58:55
User entered 'PATIENT HAD SYMPTOMS OF COVID 19 AND CALLED IN TO THE CENTER. HE RETURNED WITHIN 72 HOURS FOR ILLNESS VISIT. SYMPTOMS AND CONMEDS ARE LISTED ON APPROPRIATE PAGES IN SOURCE AND EDC. Patient tested positive at screening date 06-Aug-2020 and again on 10-Aug-2020. No further testing has been done' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 20:58:38
Query 'PV Query: Please provide the nasopharyngeal swab results from 06 Aug.' answered with 'Positive ' (Site from Safety).	(b) (4), (b) (6)	27 Aug 2020 20:56:51
Query 'Per ETRTR: COVID + Narrative should describe clinical presentation/course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' answered with 'Added' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 20:56:36
User entered 'Patient had symptoms of covid 19 and called in to the center. He returned within 72 hours for illness visit. Symptoms and conmeds are listed on appropriate pages in source and EDC' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 20:56:11
User opened query 'PV Query: Please confirm dates of all COVID-19 swabs, as well as timing of vaccination.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:55:25
User opened query 'PV Query: Please provide the nasopharyngeal swab results from 06 Aug.' (Site from Safety).	(b) (4), (b) (6)	24 Aug 2020 13:54:53
User opened query 'Per ETRTR: COVID + Narrative should describe clinical presentation/course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	20 Aug 2020 22:13:16
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:47:04

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Amendment Manager: User entered '0'	System	21 Aug 2020 02:43:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Amendment Manager: User entered 'I'	System	21 Aug 2020 02:43:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:47:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Sep 2020 21:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Sep 2020 21:45:40
Amendment Manager: User entered '0'	System	21 Aug 2020 02:43:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:43:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:47:54

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:01:50
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:46:36
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:01:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:01:23
Data point term sent to Coder	System	13 Aug 2020 18:59:46
User entered 'LISINOPRIL'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:58:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'HIGH BLOOD PRESSURE'	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '10'	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'once daily (QD)'	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 12:22:42
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	13 Aug 2020 18:58:55
User entered 'UN UNK 2015'	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4)	13 Aug 2020 18:58:55
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:58:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:58:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 18:58:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
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, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:01:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:01:23
Data point term sent to Coder	System	13 Aug 2020 18:59:46
User entered 'PRILOSEC'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 18:59:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'HEARTBURN'	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '20'	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'once daily (QD)'	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 12:22:45
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	13 Aug 2020 18:59:30
User entered 'UN UNK 2015'	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4)	13 Aug 2020 18:59:30
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 18:59:30

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
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.	(b) (4) Coder Import (b) (4)	22 Oct 2020 12:29:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 12:29:45
Data point term sent to Coder	System	22 Oct 2020 12:28:30
Coding entries removed.	Kim Calloway (b) (4)	22 Oct 2020 12:28:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
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)	13 Aug 2020 22:15:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 22:15:18
Data point term sent to Coder	System	13 Aug 2020 19:00:49
User entered 'CERTIRIZINE'	Kim Calloway (b) (4)	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 21:33:32
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of allergies. Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:01:49
Query 'Per DM CLR: Please update the indication to reflect the location and type of allergies. Review and update indication and ensure to update MH eCRF as appropriate. ' answered with ' ' (Site from DM).	Kim Calloway (b) (4)	22 Oct 2020 12:28:17
	(b) (4)	
DataPoint Un-verified.	Kim Calloway (b) (4)	22 Oct 2020 12:28:12
	(b) (4)	
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Kim Calloway (b) (4)	22 Oct 2020 12:28:12
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of allergies. Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:58:12
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'ALLERGIES'	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '10'	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'once daily (QD)'	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	15 Aug 2020 12:22:50
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	13 Aug 2020 19:00:21
User entered 'UN UNK 2015'	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4)	13 Aug 2020 19:00:21
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:00:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 06:54:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 06:54:21
Data point term sent to Coder	System	19 Oct 2020 13:49:43
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 13:49:22
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 23:31:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 23:31:16
Data point term sent to Coder	System	13 Aug 2020 19:22:51
User entered 'PEPCID'	Kim Calloway (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4)	13 Aug 2020 19:21:59
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:03:58
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:49:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:49:22
User entered 'STOMACH COATING/ACID REFLUX' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 13:49:22
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:14:16
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'STOMACH COATING'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '40'	Kim Calloway (b) (4)	13 Aug 2020 19:21:59
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	Kim Calloway (b) (4)	13 Aug 2020 19:21:59
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:21:59
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'twice daily (BID)'	Kim Calloway (b) (4)	13 Aug 2020 19:21:59
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:21:59
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4)	13 Aug 2020 19:21:59
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:21:59
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020'	Kim Calloway (b) (4)	13 Aug 2020 19:21:59
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4)	13 Aug 2020 19:21:59
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 19:21:59
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:21:59
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:08:31
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'CORRECTED' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 18:49:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 13:50:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 13:50:15
User entered 'No (N)' reason for change: Data Entry Error	System	19 Oct 2020 13:50:15
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 13:50:15
DataPoint Un-verified.	System	19 Oct 2020 13:50:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 13:50:07
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 10:14:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 17:47:05
	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:21:59

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
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.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 23:36:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 23:36:38
Data point term sent to Coder	System	19 Oct 2020 13:51:44
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 13:51:14
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
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) (b) (4)	14 Aug 2020 22:48:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 22:48:53
Data point term sent to Coder	System	13 Aug 2020 19:23:55
User entered 'FLONASE'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4)	13 Aug 2020 19:23:33
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 18:49:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:51:14
User entered 'SINUS CONGESTION/ COVID 19'	(b) (4), (b) (6)	19 Oct 2020 13:51:14
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'SINUS CONGESTION'	Kim Calloway (b) (4)	13 Aug 2020 19:23:33
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'I'	Kim Calloway (b) (4)	13 Aug 2020 19:23:33
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Other (OTHER)'	Kim Calloway (b) (4)	13 Aug 2020 19:23:33
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'SQUIRT'	Kim Calloway (b) (4)	13 Aug 2020 19:23:33
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'once daily (QD)'	Kim Calloway (b) (4)	13 Aug 2020 19:23:33
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:23:33
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Nasal (NASAL)'	Kim Calloway (b) (4)	13 Aug 2020 19:23:33
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:23:33
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020'	Kim Calloway (b) (4)	13 Aug 2020 19:23:33
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4)	13 Aug 2020 19:23:33
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per CDM re-query: Response states 'ADDED' however medication is still checked as Ongoing and no End Date has been recorded. Please review and update as appropriate per previous query.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:30:51
Query 'Per CDM re-query: Response states 'ADDED' however medication is still checked as Ongoing and no End Date has been recorded. Please review and update as appropriate per previous query.' answered with 'Patient has had ongoing sinusitis and medication is continuing. will update if it changes' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:20:24
User opened query 'Per CDM re-query: Response states 'ADDED' however medication is still checked as Ongoing and no End Date has been recorded. Please review and update as appropriate per previous query.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:05:41
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:05:41
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 'ADDED' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:51:34
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:13:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:23:33
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:04:13
	(b) (4), (b) (6)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with '.' (Site from DM). DataPoint Un-verified.	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:35:27
	Kim Calloway (b) (4)	15 Oct 2020 03:35:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	15 Oct 2020 03:35:21
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 10:13:19
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:23:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:23:33

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:23:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: ZINC ACETATE;ZINC GLUCONATE, PRODUCTSYNONYM: ZICAM COLD REMEDY [ZINC ACETATE;ZINC GLUCONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 13:11:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 13:11:38
Data point term sent to Coder	System	17 Dec 2020 18:36:20
Coding entries removed.	(b) (4), (b) (6)	17 Dec 2020 18:35:45
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: ZINC ACETATE;ZINC GLUCONATE, PRODUCTSYNONYM: ZICAM COLD REMEDY [ZINC ACETATE;ZINC GLUCONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:35:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 18:35:44
Data point term sent to Coder	System	25 Aug 2020 18:10:05
User closed query 'For coding purposes, references indicate different formulations for ZYCAM. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	System	25 Aug 2020 18:09:17
Query 'For coding purposes, references indicate different formulations for ZYCAM. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' answered with 'updated' (Site from System).	Kim Calloway (b) (4)	25 Aug 2020 18:09:17
User entered 'ZICAM (zinc acetate and zinc gluconate)' reason for change: Data Entry Error	Kim Calloway (b) (4)	25 Aug 2020 18:09:12

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Aug 2020 17:23:02
User entered 'ZICAM' reason for change: Data Entry Error	Kim Calloway (b) (4)	24 Aug 2020 17:22:34
User opened query 'For coding purposes, references indicate different formulations for ZYCAM. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	Coder Import (b) (4)	16 Aug 2020 12:26:07
Data point term sent to Coder	System	13 Aug 2020 19:25:01
User entered 'ZYCAM'	Kim Calloway (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:20:56
User closed query 'Per DM CLR: Please be advised there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 06:33:02
Query 'Per DM CLR: Please be advised there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 18:36:36
DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 18:35:45
User entered 'Covid-19' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 18:35:45
User opened query 'Per DM CLR: Please be advised there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:02:03
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)	02 Nov 2020 15:43:43
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).	(b) (4), (b) (6)	30 Oct 2020 18:24:50

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
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)	30 Oct 2020 13:09:37
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'COUGH'	Kim Calloway (b) (4)	13 Aug 2020 19:24:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'l'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'tablet (TABLET)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'as needed (PRN)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020' reason for change: Data Entry Error	Kim Calloway (b) (4)	13 Aug 2020 19:26:09
User entered '10 Aug 2020'	(b) (4) Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:33:32
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:24:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:24:38
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:33:32
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	30 Oct 2020 18:25:25
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:25:25
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	30 Oct 2020 18:24:38
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:24:38
User entered '13 Apr 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:24:38
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:05:53
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with '.' (Site from DM).	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:35:56
DataPoint Un-verified.	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:35:52
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:35:52
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:16:44
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User entered empty.	System	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User entered empty.	System	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:06
User entered empty.	System	13 Aug 2020 19:24:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 23:15:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 23:15:37
Data point term sent to Coder	System	05 Nov 2020 16:50:44
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 16:50:43
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 21:21:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 21:21:13
Data point term sent to Coder	System	13 Aug 2020 19:26:07
User entered 'BENZONATE'	Kim Calloway (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR-REQUERY: Response to previous query is noted. However, please update CM indication term to reconcile with recorded AE term so there is an appropriate match. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 10:34:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:55:31
Query 'Per DM CLR-REQUERY: Response to previous query is noted. However, please update CM indication term to reconcile with recorded AE term so there is an appropriate match. Please update accordingly. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:50:49
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 16:50:43
User entered 'Covid-19' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:50:43
User opened query 'Per DM CLR-REQUERY: Response to previous query is noted. However, please update CM indication term to reconcile with recorded AE term so there is an appropriate match. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:01:43
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)	02 Nov 2020 15:43:59
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 AE is added as Covid per DM and CRA' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:26:21

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
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)	30 Oct 2020 13:09:52
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'COUGH'	Kim Calloway (b) (4)	13 Aug 2020 19:25:56
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '200'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User closed query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 19:37:13
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with '.' (Site from DM).	Kim Calloway (b) (4) (b) (4)	17 Sep 2020 22:27:54
User entered 'four times daily (QID)' reason for change: Per Query Resolution	Kim Calloway (b) (4) (b) (4)	17 Sep 2020 22:27:49
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 15:45:55
User entered 'other (OTHER)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty; reason for change Data Entry Error	Kim Calloway (b) (4)	17 Sep 2020 22:27:49
User entered 'EVERY 8 HOURS'	(b) (4) Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '10 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:33:32
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:25:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:25:45
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:33:32
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:25:45
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:25:45
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:05:58
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with '.' (Site from DM).	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:36:16
DataPoint Un-verified.	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:36:11
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:36:11
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:15:47
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:25:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User entered '4'	System	17 Sep 2020 22:27:49
User entered empty.	System	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User entered '1'	System	17 Sep 2020 22:27:49
User entered empty.	System	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:10
User entered '804 (804)'	System	17 Sep 2020 22:27:49
User entered empty.	System	13 Aug 2020 19:25:56

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
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)	19 Oct 2020 21:57:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 21:57:30
Data point term sent to Coder	System	19 Oct 2020 13:52:45
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 13:51:54
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
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)	14 Aug 2020 06:06:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 06:06:11
Data point term sent to Coder	System	13 Aug 2020 19:28:13
User entered 'ALBUTEROL PRO AIR'	Kim Calloway (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR: Please confirm if this is related to AE#5 COIVD-19 (06AUG2020). If not, please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 06:33:29
Query 'Per DM CLR: Please confirm if this is related to AE#5 COIVD-19 (06AUG2020). If not, please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'indication shows covid 19' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 18:37:23
User opened query 'Per DM CLR: Please confirm if this is related to AE#5 COIVD-19 (06AUG2020). If not, please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:03:13
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:49:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 13:51:54
User entered 'CHEST CONGESTION/ COVID 19' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 13:51:54
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'CHEST CONGESTION'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:09:20
User closed query 'Per CDM re-query: Dose per Administration should be a numerical response only. Please remove the units from this field and update the Dose Unit field as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 09:42:36
Query 'Per CDM re-query: Dose per Administration should be a numerical response only. Please remove the units from this field and update the Dose Unit field as appropriate.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:32:16
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 18:32:08
User entered '32' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 18:32:08
User opened query 'Per CDM re-query: Dose per Administration should be a numerical response only. Please remove the units from this field and update the Dose Unit field as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:39:17
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)	06 Nov 2020 10:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:55:31
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 'corrected' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:51:13
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 16:51:07
User entered '32mg' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:51:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
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)	03 Nov 2020 09:03:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '2'	Kim Calloway (b) (4)	13 Aug 2020 19:27:44
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:09:20
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 18:32:08
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 18:32:08
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'puff (PUFF)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'as needed (PRN)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 07 AUG 2020.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 09:42:54
' (Site from DM).		
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 07 AUG 2020.	(b) (4), (b) (6)	06 Nov 2020 18:32:25
' answered with 'per patient this is correct' (Site from DM).		
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 07 AUG 2020.	(b) (4), (b) (6)	06 Nov 2020 10:13:56
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:33:32
User closed query ' Per CDM re-query: Response states 'ADDED' however medication is still checked as Ongoing and no End Date has been recorded. Please review and update as appropriate per previous query' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:44:11
Query ' Per CDM re-query: Response states 'ADDED' however medication is still checked as Ongoing and no End Date has been recorded. Please review and update as appropriate per previous query' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:24:05
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:23:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:23:59
User opened query ' Per CDM re-query: Response states 'ADDED' however medication is still checked as Ongoing and no End Date has been recorded. Please review and update as appropriate per previous query' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:06:41
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:06:41
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 'ADDED' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:52:00
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:10:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:33:32
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:23:59
User entered '13 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:23:59
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:06:43
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with '.' (Site from DM).	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 01:49:54
DataPoint Un-verified.	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 01:49:48
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 01:49:48
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:10:20
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:27:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User entered empty.	System	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User entered empty.	System	13 Aug 2020 19:27:44

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:13
User entered empty.	System	13 Aug 2020 19:27:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID, PRODUCTSYNONYM: OMEGA 3 [DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 11:54:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 11:54:44
Data point term sent to Coder	System	25 Aug 2020 18:07:57
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	25 Aug 2020 18:07:55
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	Kim Calloway (b) (4) (b) (4)	25 Aug 2020 18:07:55
User entered 'OMEGA 3 ACID (alpha-linolenic acid, eicosapentaenoic acid, and docosahexaenoic acid)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	25 Aug 2020 18:07:42
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	18 Aug 2020 12:28:20
Data point term sent to Coder	System	13 Aug 2020 19:30:16

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'OMEGA 3 ACID'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'IMMUNE HEALTH'	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'I'	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'g (g)'	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'twice daily (BID)'	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020'	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:29:57
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:06:48
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate. ' answered with '.' (Site from DM).	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 01:49:15
DataPoint Un-verified.	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 01:49:10
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 01:49:10
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:11:21
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:29:57

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
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) (b) (4)	14 Aug 2020 01:19:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 01:19:09
Data point term sent to Coder	System	13 Aug 2020 19:32:22
User entered 'VITAMIN C'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'IMMUNE BOOST'	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'I'	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'tablet (TABLET)'	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'once daily (QD)'	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020'	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:31:26
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:06:53
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate.' answered with '.' (Site from DM).	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:36:45
DataPoint Un-verified.	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:36:41
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:36:41
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:17:30
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:31:26

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 19:33:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 19:33:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 19:33:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 19:33:12
Data point term sent to Coder	System	13 Aug 2020 19:32:23
User entered 'MULTIVITAMIN'	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'SUPPLEMENT'	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'I'	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'tablet (TABLET)'	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'once daily (QD)'	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '07 Aug 2020'	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	Kim Calloway (b) (4)	13 Aug 2020 19:32:13
	(b) (4)	

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:06:57
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 18:49:57
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate. ' answered with ' (Site from DM).	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:37:09
DataPoint Un-verified.	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:37:05
User entered 'No (N)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	15 Oct 2020 03:37:05
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol and is also a prophylactic medication. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:11:59
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	Kim Calloway (b) (4) (b) (4)	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:32:13

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 12:04:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 12:04:33
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	30 Mar 2021 14:21:29 30 Mar 2021 14:21:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 09:53:55
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 09:53:55
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	17 Nov 2020 16:37:32 17 Nov 2020 16:36:50
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 06:37:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 06:37:35
Data point term sent to Coder	System	08 Sep 2020 17:54:31
User entered 'Augmentin/Clavulanic acid'	(b) (4), (b) (6) (b) (4)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:20:56
User closed query 'Per CDM re-query: Response noted; Please update the indication to match MH term in MH log #8 (CHRONIC SINUSITIS) if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 14:04:21
Query 'Per CDM re-query: Response noted; Please update the indication to match MH term in MH log #8 (CHRONIC SINUSITIS) if appropriate. Thank you.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:21:16
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 14:21:07
User entered 'WORSENING OF CHRONIC SINUSITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 14:21:07
User closed query 'Per DM CLR: This Con Med was added on 03Sep2020. Please clarify if the medical history condition required a change in the medication. If yes, please add the applicable AE entry or explain the reason for the change in regimen.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:04:51
User opened query 'Per CDM re-query: Response noted; Please update the indication to match MH term in MH log #8 (CHRONIC SINUSITIS) if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:04:49
Query 'Per DM CLR: This Con Med was added on 03Sep2020. Please clarify if the medical history condition required a change in the medication. If yes, please add the applicable AE entry or explain the reason for the change in regimen.' answered with 'Patient has chronic sinusitis that is often treated with antibiotics. Information is correct' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 21:34:27
User opened query 'Per DM CLR: This Con Med was added on 03Sep2020. Please clarify if the medical history condition required a change in the medication. If yes, please add the applicable AE entry or explain the reason for the change in regimen.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:18:54

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR RQ: Response to previous query noted 'corrected', however, there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:27:21
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:09:20
Query 'Per DM CLR RQ: Response to previous query noted 'corrected', however, there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.	(b) (4), (b) (6)	17 Nov 2020 16:37:05
' answered with 'Not an AE see medical history' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:36:50
User entered 'Worsening of SINUSITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:36:50
User opened query 'Per DM CLR RQ: Response to previous query noted 'corrected', however, there is still no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.	(b) (4), (b) (6)	06 Nov 2020 10:17:53
' (Site from DM).		
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.	(b) (4), (b) (6)	20 Oct 2020 14:59:35
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.	(b) (4), (b) (6)	06 Oct 2020 16:29:55
' answered with 'corrected' (Site from DM).		

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 11:27:16
User entered 'Sinusitis'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '825/125'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:54:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'twice daily (BID)'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '03 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:09:20
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:36:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:36:50
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:09:20
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:36:50
User entered '13 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:36:50
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User entered '2'	System	08 Sep 2020 17:54:16

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User entered '1'	System	08 Sep 2020 17:54:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:43
User entered '804 (804)'	System	08 Sep 2020 17:54:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 09:53:56
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 09:53:56
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #12. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:41:52
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	17 Nov 2020 16:38:33 17 Nov 2020 16:37:47
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #12. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:37:21
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #12. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:19:36
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:03:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:03:12
Data point term sent to Coder	System	06 Oct 2020 17:02:11
User entered 'AUGMENTIN/CLAVULANIC ACID'	(b) (4), (b) (6) (b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 11:27:39
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 19:09:20
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Not an AE see medical history' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:38:01
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:37:47
User entered 'Worsening of SINUSITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:37:47
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:19:31
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Sinusitis'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:33:32
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 15:44:29
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:27:28
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:27:22
User entered '875/125' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:27:22
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:09:05
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '875'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'twice daily (BID)'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '02 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

US3452295

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:09:20
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:37:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:37:47
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:09:20
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:37:47
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:37:47
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 17:02:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 03:16:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:47:05
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 17:02:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User entered '2'	System	06 Oct 2020 17:02:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User entered '1'	System	06 Oct 2020 17:02:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:47:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:39:47
User entered '804 (804)'	System	06 Oct 2020 17:02:10

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:47:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
User entered 'No (N)'	Destiny	08 Feb 2021 16:47:38
	Heinzig-Cartwright (b) (4)	
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:47:54

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:01:02
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:51:15
User entered '10 Aug 2020'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 17:16:50

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:47:54

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:01:02
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:51:15
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 19:32:18
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 19:30:07
User entered 'Due to SARS-COV-2 (COVID)'	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 17:16:50

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:47:54

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:01:02
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:51:15
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	07 Oct 2020 19:32:18
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	07 Oct 2020 19:30:07
User entered empty.	Kim Calloway (b) (4) (b) (4)	07 Oct 2020 17:16:50

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Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered	System	19 Aug 2020 13:39:54
'USA-US208-2020-MRNA-1273-P301000001'		

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Death

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'CARL'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

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Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'GRIFFIN'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

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Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '3555 NW 58TH STREET'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OKC'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OK'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '73112'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:14:13
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 15:39:40
User entered 'US' (non-conformant).	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Sep 2020 02:07:54
User entered '2'	System	28 Aug 2020 15:40:06
User entered '1'	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered	System	19 Aug 2020 13:39:54
'USA-US208-2020-MRNA-1273-P301000001'		

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'CARL'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'GRIFFIN'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '3555 NW 58TH STREET'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OKC'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OK'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '73112'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:14:13
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 15:39:40
User entered 'US' (non-conformant).	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Sep 2020 02:07:54
User entered '2'	System	28 Aug 2020 15:40:06
User entered '1'	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:47:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered '19/Aug/2020 09:40'	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:47:54

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.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 15:39:40
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered	System	19 Aug 2020 13:39:54
'USA-US208-2020-MRNA-1273-P301000001'		

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'CARL'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'GRIFFIN'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '3555 NW 58TH STREET'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OKC'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OK'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '73112'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:14:13
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 15:39:40
User entered 'US' (non-conformant).	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Sep 2020 02:07:54
User entered '2'	System	28 Aug 2020 15:40:06
User entered '1'	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:47:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered '28/Aug/2020 11:40'	System	28 Aug 2020 15:40:06

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:47:54

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.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered 'I'	(b) (4), (b) (6)	28 Aug 2020 15:40:06

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered	System	19 Aug 2020 13:39:54
'USA-US208-2020-MRNA-1273-P301000001'		

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Death

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Reviewed for Safety.	(b) (4), (b) (6)	19 Aug 2020 13:40:23
User entered 'No (N)'	System	19 Aug 2020 13:39:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'CARL'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'GRIFFIN'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '3555 NW 58TH STREET'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OKC'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered 'OK'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered empty.	System	21 Sep 2020 21:48:14
User entered '73112'	April Green (b) (4)	18 Sep 2020 00:52:08
	(b) (4)	

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Oct 2020 17:42:07
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:14:13
Reviewed for Safety.	(b) (4), (b) (6)	28 Aug 2020 15:39:40
User entered 'US' (non-conformant).	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:47:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Sep 2020 02:07:54
User entered '2'	System	28 Aug 2020 15:40:06
User entered '1'	System	19 Aug 2020 13:40:30

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:47:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered '09/Sep/2020 22:07'	System	10 Sep 2020 02:07:54

US3452295

Folder: SAE USA-US208-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:47:54

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.	Carl Griffin (b) (4)	16 Apr 2021 21:45:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 17:42:07
User entered 'I'	(b) (4), (b) (6)	10 Sep 2020 02:07:54